

the Notes

News from the hospital on Harley Street | Issue 10

Clinical trials service launched at The London Clinic

Alistair Gifford Moore, Advanced Therapy Centre Manager discusses the new service developed to offer potentially groundbreaking new treatments

Alistair Gifford Moore
Clinical Trials Manager



leading expertise, the ATC will benefit from the facilities and a wealth of experience within our research team and the Clinic's consultants.

The Advanced Therapies Centre offers:

- Conduct Phase II & III clinical trials and medical devices trials
- Provide training for clinic staff on clinical trials and GCP
- Support fast set up compared to NHS trusts
- Allow access to trial naive population with out conflicting studies
- Facilitate Novel therapies and leading treatment innovations

The ATC looks to establish an internationally recognised clinical trial facility and provide Clinic patients' access to Investigational Medicinal Products (IMP) that are currently only available through the NHS. The focus will be on phase II and phase III trials.

The Centre will also provide facilities

for named patient programmes which will enable doctors to access medicines that are still under development or not routinely available in a controlled hospital environment. It will also support consultants and specialists at The London Clinic to set up and run clinical trials.

Our first clinical trials are focussing on Oncology and will include studies of immunotherapy, agents in pancreatic and other forms of malignancy. Studies are also planned to stabilise patients with multiple myeloma and a comparison of the superiority of stereotactic radiosurgery with CyberKnife for cancers that have metastasized.

The ATC key service offering

- Central coordination of clinical trials providing quicker setups and results with half the R&D approval time compared to the NHS
- The provision of a consultant led service, using internationally acclaimed experts; ensuring a high level consistent service. It will also support consultants' research at the Clinic
- Named Patient program provides access to unlicensed medications
- Rapid patient recruitment through links to our consultants' NHS practices →

The London Clinic's new Advanced Therapies Centre (ATC) will provide innovative treatment choices for Clinic patients by supporting Clinical Trials, and Named Patient Program enabling access to novel therapies.

The introduction of a clinical trial program in the independent healthcare sector allows equal access for private patients to new treatments and clinical trials as currently offered by the NHS. Based in the Clinic's new £90 million cancer centre which is equipped with the latest treatment, technology and world



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“We offer patients the latest advances in treatments whilst adhering to the strict UK legislation regulating the use of investigational medicinal products in clinical trials.”

Alistair Gifford Moore

- Support approval process for sponsors from both the industry and academia
- Quality assurance checks for all research at ATC with a quality management systems.
- Monitoring and treatment in the UK's largest independently owned hospital dedicated to personalised healthcare, medical expertise and patient comfort

Patients come first

We offer patients the latest advances in treatments whilst adhering to the strict UK legislation regulating the use of investigational medicinal products in clinical trials. The Advanced Therapies Centre is also required to follow detailed NHS regulations on study processes and data collection.

All trial protocols will be submitted to the Clinical Trials Manager for review, will undergo a risk assessment and review by the Research Advisory Group, and then be reviewed by The London Clinic Ethics Committee. Regular reporting and monitoring will be undertaken as the trial gets underway, with an extended report submitted to the Committee annually. We will also encourage GPs and consultants to discuss with their patients about whether a clinical trial is right for them.

The London Clinic is at the forefront of cancer care with access to new equipment and expertise for the latest treatment options available. We have outstanding research talent and cutting edge equipment such as the CyberKnife Robotic Radiosurgery System and the Da Vinci S Robotic Surgical System.

Current and proposed trials

- A randomised, open-label, proof-of-concept, phase II trial comparing Gemcitabine with and without IMM-101 in advanced pancreatic cancer
- A study on the impact of stem cell donation and bone marrow harvesting on voluntary unrelated donors on the Anthony Nolan Bone Marrow Register and the NHSBT British Bone Marrow Register (BBMR).

The Advanced Therapies Centre consists of a multi-disciplinary team made up of specialist pharmacists, research governance and quality assurance facilitators, a Macmillan Cancer Information Nurse Specialist and consultant advisors from the NHS, academia and the pharmaceutical industry.

Alistair Gifford Moore

Clinical Trials Manager

The London Clinic Advanced Therapies Centre
22 Devonshire Place | London | W1G 6JA

T: 020 3219 3570 | F: 020 7616 7670 | E: atc@thelondonclinic.co.uk

Dr Joe Brookes
FRCR FRCP
Consultant
Endovascular
Radiologist



Are varicose veins and ulcers a 'Low Priority'? Not for the sufferers!

The first UK endovenous laser cases for chronic venous insufficiency and varicose veins were carried out over 10 years ago at The Middlesex Hospital.

Surgical high-tie crosssection and stripping of the saphenous veins had reigned supreme for 30 years and a clinical debate ensued. With the availability of grade 1 RCT evidence comparing endovenous laser ablation treatment with surgery, the case is now generally accepted as the new 'Gold standard'.¹

Further development continues comparing the two leading thermal techniques of laser and radiofrequency ablation and in the treatment of incompetent perforators and varicose ulcers. Delivery has also advanced through new wavelengths with selective absorption characteristics and local tumescent anaesthesia such that treatment has moved from general to local anaesthesia, inpatient to outpatient care, OR to office delivery. Days of making mothers wait 'until your child-bearing years are over' and 3-6 weeks recovery times are well and truly over.

It's ironic that just as these new minimally invasive techniques are available for such a common scourge, affecting around 15% of adults, the downturn in the NHS is placing these relatively cheap and very effective remedies out of reach for many.

Not all those with varicose veins will progress to ulceration, with an ageing population and diminished public care, an increased incidence of varicose

ulceration will likely place an added unintended burden on overstretched services. Treatment at an earlier age and stage prevents the secondary complications of Chronic Venous Insufficiency (CVI) which is what the new treatments offer.

At The London Clinic, we have a long established minimally-invasive service for varicose veins, ulcers and related conditions. Competitive packages open this service to those excluded from treatment within the NHS by the 'low priority procedure' regulations.

Accurate assessment at consultation with duplex scanning is the key to successful treatment. The identification and exclusion of condition and syndromes mimicking varicose veins is vital.

Identification of variations such as Pelvic Venous Incompetence (PVI) with secondary drainage to the leg veins will alter the treatment schedule significantly.

PVI (ovarian vein incompetence - a variant of 'pelvic congestion syndrome' or 'Female varicocele') has been increasingly



Fig 5. Cirrhosis with portosystemic hypertension draining via umbilical vein to left long saphenous vein could cause a nasty surprise!

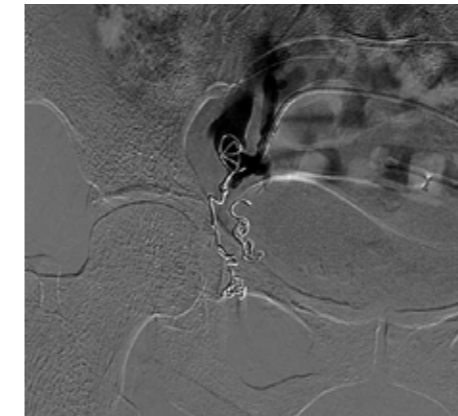


Fig 7. Incompetence eliminated by coil embolisation



Fig 6. Right Internal iliac branch incompetence to vulval and buttock varices

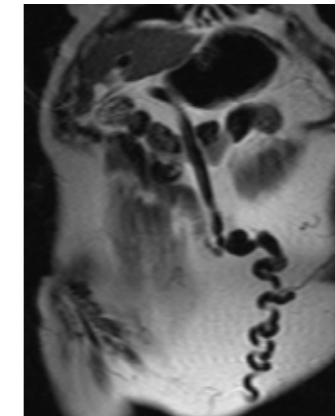


Fig 8. Completion of Pelvic venous embolisation for four vessel incompetence

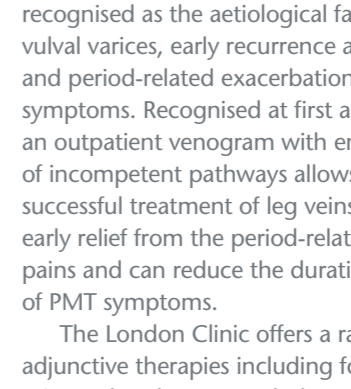


Fig 6. Right Internal iliac branch incompetence to vulval and buttock varices

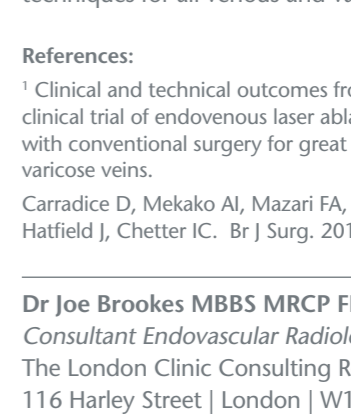


Fig 8. Completion of Pelvic venous embolisation for four vessel incompetence

Fig 1. Right Long saphenous incompetence (presenting with spontaneous bruising behind knee)

Fig 2. Same patient 10 days after endovenous laser treatment

Fig 3. Ulcer 14th March

Fig 4. Same ulcer after endovenous laser. 29th April

recognised as the aetiological factor behind vulval varices, early recurrence after surgery and period-related exacerbation of leg vein symptoms. Recognised at first assessment, an outpatient venogram with embolic coiling of incompetent pathways allows subsequent successful treatment of leg veins. It also affords early relief from the period-related leg (thigh) pains and can reduce the duration and severity of PMT symptoms.

The London Clinic offers a range of adjunctive therapies including foam and micro-sclerotherapy, ambulatory phlebectomy and percutaneous laser treatments, and a full range of surgical and interventional radiology techniques for all venous and vascular disease.

References:

¹ Clinical and technical outcomes from a randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins.

Carradice D, Mekako AI, Mazari FA, Samuel N, Hatfield J, Chetter IC. Br J Surg. 2011 Jun 3.

Dr Joe Brookes MBBS MRCP FRCR

Consultant Endovascular Radiologist

The London Clinic Consulting Rooms

116 Harley Street | London | W1G 7JL

T: 020 7616 7795

E: j.brookes@thelondonclinic.co.uk

Improving long-term outcomes for patients with glaucoma

Mr Avi Kulkarni discusses the challenges in managing patients with glaucoma and how best to optimize their care



Glaucoma is the commonest cause of irreversible blindness worldwide, with over 60 million people affected. 1% of the total population in the UK and 2% of those over 40 have glaucoma. The majority of glaucoma patients are asymptomatic until late in the course of their disease. With late diagnosis, patients typically have extensive, irreversible, peripheral visual field loss, and characteristic optic disc cupping with neuroretinal rim loss and marked retinal nerve fibre layer loss (Fig.1). Screening for glaucoma is therefore essential to detect cases early.

Early Detection

Glaucoma screening is undertaken by community optometrists and ophthalmic medical practitioners as part of the NHS general ophthalmic services, and is predominantly responsible for the detection of glaucoma in the community. Despite this, up to 50% of patients with glaucoma remain undiagnosed and late presentation with end-stage disease is not uncommon. Certain groups are particularly at risk of delayed diagnosis; those with limited access to healthcare for socio-economic reasons and certain ethnic groups e.g. African and Caribbeans who present earlier and progress more rapidly.

Treatment

Medical treatment for glaucoma is well established and highly effective in most cases, poor adherence and limited persistence with ocular hypotensive drops is a common problem and complicates management. Studies show that, in addition to patients not using their drops as prescribed, at best only 70% of patients obtain a further prescription for their drops once their initial supply is finished. Furthermore, patients are more likely to obtain a repeat prescription for a prostaglandin analogue (PGA) such as latanoprost, compared to other drops. Evidence suggests the best

adherence and persistence rates occur with the use of PGAs particularly latanoprost too. Rates are reduced for beta-blockers e.g. timolol, alpha-agonists e.g. brimonidine, and carbonic-anhydrase inhibitors e.g. dorzolamide. Factors contributing to such variations include dosing regimen, with single dose agents like PGAs showing better rates of adherence and persistence. Intolerable adverse effects contribute to reduced adherence and persistence and explain why beta-blockers (systemic side effects e.g. dyspnoea, impotence), alpha-agonists, and carbonic anhydrase inhibitors (local side effects e.g. drop allergy) are less well tolerated.

Differentiating true disease progression from under-treatment due to poor adherence and persistence can be difficult but taking a careful history at the initial consultation will highlight important risk factors. Occupational issues including long working hours, overseas travel and nightshift work make drop adherence difficult. Patients may not admit to side effects such as beta-blocker-induced impotence. Consideration is important for elderly patients with arthritic hands who experience difficulty instilling drops and is resolved through choosing a soft-bodied easily opened bottle. Finally, frequent clinic non-attendance is frequently associated with poor adherence.

The initial consultation at the time of diagnosis is critical in determining how well a patient will follow a new treatment regimen. As glaucoma is usually asymptomatic, patients have no indication as to the effectiveness of their medication and satisfactory adherence requires a thorough understanding of their condition and a belief that their treatment will help preserve vision. Table 1 outlines measures to help ensure patients use their medication effectively.

Surgery

In some cases, maximal, topical medical therapy fails to prevent optic disc damage and progressive visual field loss. In others, topical

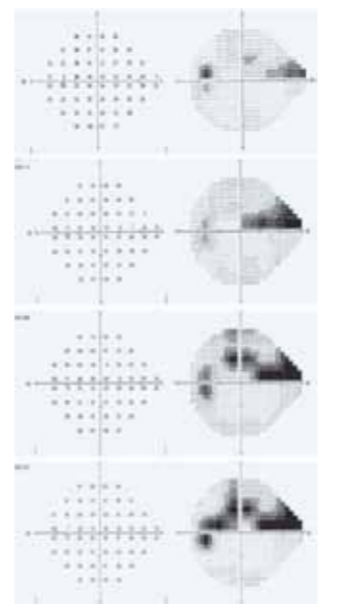
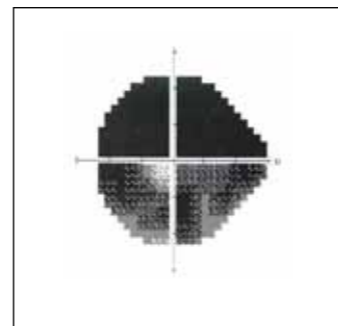


Figure 1 Glaucomatous optic neuropathy, and progressive, glaucomatous visual field loss

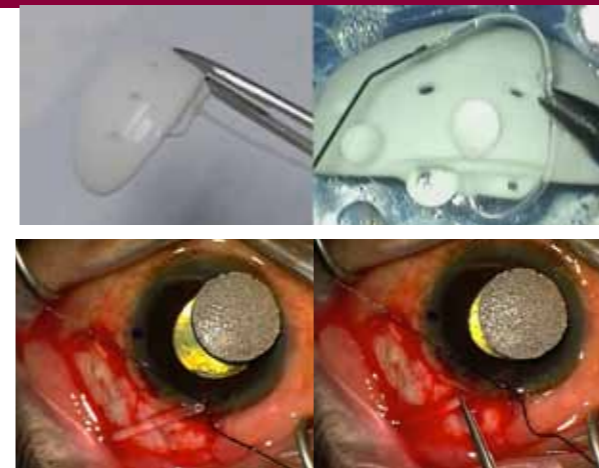


Fig. 2. Baerveldt tube: priming prior to insertion; insertion of the tube into the anterior chamber during surgery

medication produces intolerable side effects necessitating an alternative treatment modality.

For these patients glaucoma surgery provides a definitive solution to lower intraocular pressure (IOP) and arrest disease progression, without the need for topical, ocular hypotensive medication. Modern advances in surgical techniques minimise the risk of postoperative complications and increase the chances of long-term IOP control. The intraoperative application of antimetabolites such as mitomycin-C during trabeculectomy in high-risk cases, minimizes the degree of postoperative, subconjunctival scarring, and increases the chances of surgical success. In cases of refractory or secondary glaucoma, trabeculectomy is less effective, and glaucoma drainage implant surgery provides the best chance of long-term IOP control. Modern devices such as the Ahmed valve and Baerveldt tube are effective in maintaining low IOP in these difficult cases (Fig.2). Thorough patient counselling and careful choice of surgical procedure help to ensure the best long-term outcomes.

Summary

The technical management of glaucoma is relatively straightforward with medical and surgical therapy titrated against IOP, optic disc damage and visual field loss. However it is important that non-medical factors can profoundly affect the effectiveness of treatment, and a holistic approach to managing glaucoma patients provides the best chance of minimising visual loss.

Table 1 Measures to improve adherence and persistence with medication

- Patient education (written and verbal)
- Assessment of response to initiation of topical therapy and adverse effects
- Awareness of 'white coat adherence'
- Assessment of patients' ability to instil drops
- Written daily dosing instructions
- Assessing patients' lifestyles
- Reminder text messages/ phone calls
- Ensure reliable means for patient communication

Mr Avi Kulkarni BSc FRCSEd
Consultant Ophthalmic Surgeon and Glaucoma Specialist
The London Clinic Eye Centre | 149 Harley Street | London W1G 6DE
T: 07411 081 381 E: avikulkarnipa@aol.com

Consultant Profile



Professor Peter Harris
Consultant Vascular
and Endovascular
Surgeon

Professor Peter Harris is Professor of Endovascular Surgery at University College London and Head of Vascular and Endovascular Surgery at University College London Hospitals.

He has extensive clinical experience in all aspects of vascular and endovascular surgery with an interest in arterial disease such as open and endovascular surgical management of aneurysms including those affecting the abdominal, thoracic and thoraco-abdominal aorta. He is also experienced in carotid artery reconstruction for prevention of stroke and angioplasty, stenting and bypass surgery for relief of circulatory impairment affecting the limbs.

Professor Harris' research interests are in endovascular treatment of aortic aneurysms and arterial bypass surgery for limb salvage in patients with severe circulatory impairment and he has pioneered new treatments in both of these fields. He also established one of the UK's first programmes for endovascular repair of aortic aneurysms, in Liverpool in the early 1990's.

He has held several offices including President of the Vascular Society of Great Britain and Ireland, President of the European Union Board of Vascular Surgery and UK Representative for the International Council of the International Society for Endovascular Specialists.

At The London Clinic and at his NHS practice, Professor Harris leads a strong multidisciplinary team, which includes all the specialist skills required for modern vascular and endovascular surgical practice to the highest international standards.

Professor Peter Harris MD FRCS
Consultant Vascular and Endovascular Surgeon

The London Clinic Consulting Rooms
5 Devonshire Place | London | W1G 6BW
T: 020 7881 0683
E: jenniecronin@hotmail.co.uk



Notes from matron

Matron provides an update on recent developments and new services in the Clinic

Amanda Hallums
Matron/Director of Clinical Services

The London Clinic gains Macmillan Quality award

We've been awarded a Macmillan Quality Environment Mark (MQEM) for the high standards of care offered by our Richard Hambro Macmillan Cancer Information Centre to people affected by cancer.

Stephen Richards, Macmillan's Director for England presented the award to Michael Abrahams, our Chairman and Alison Boyd, our Cancer Information Nurse Specialist on Monday 27 June.

The Macmillan award is the first in the UK that promotes best practice and measures excellence across a series of key performance indicators shaped by people living with and beyond cancer.

To achieve the award, we had to ensure that our centre scored highly for our use of space, comfort and atmosphere, personal and social interaction, user involvement, consideration of privacy and dignity, and health and wellbeing. Consideration was also given to how people were greeted,



Above (l to r): Michael Abrahams, Chairman of The London Clinic and Alison Boyd, our Cancer Information Nurse Specialist pictured with Stephen Richards, Macmillan's Director for England

the use of natural light and the availability of quiet, private rooms.

Mr Richards said: "The London Clinic achieved a high rating in all areas that are categorised as 'really important' by people living with cancer who helped develop

the award. This reflects the hard work and dedication of the team that designed the centre and the Nurse Specialist and volunteer who work in it to make it a welcoming and supportive environment for patients and their families."

The London Clinic invited to be on Aviva's Key Hospital List

Sanjay Shah, Chief Financial Officer at The London Clinic

We are very proud to announce that the Clinic has been invited to join Aviva's Key Hospital List. This is a directory of hospitals that Aviva's UK customers who select the PMI Key hospital list can access.

We are delighted that the Clinic is one of the very few private hospitals in Central London to be selected. We have been treating Aviva customers for over 20 years and we are delighted that all of Aviva's customers who have selected the UK PMI Key and Extended hospital lists will now be able to access our leading edge facilities, with the highest standard of medical and surgical care available in the UK.



New Kidney Centre launched



We are pleased to introduce The London Clinic Kidney Centre, providing comprehensive outpatient and inpatient services for patients with kidney disease. The centre consists of a team of nephrologists who each cover all aspects of nephrology, dialysis and transplantation, with specialised expertise that spans a diverse range of kidney conditions. Dr Jennifer Cross, Professor John Cunningham, Dr Alan Salama and Dr Robin Woolfson are all pleased to review patients for investigation and management of all forms of kidney disease, including acute kidney injury, dialysis and transplantation, as well as general internal medicine, hypertension and metabolic diseases.

Services include:

- Acute Kidney injury
- Cancer and haematological associated renal disorders including myeloma, a myloid and cryoglobulinaemia
- Chronic Kidney disease
- Diabetic nephropathy
- Dialysis (all modalities)
- Fluid and electrolyte disorders
- General internal medicine
- Genetic renal diseases
- Glomerular and tubulointerstitial disease
- Hypertension (essential, secondary and 'difficult')
- Intensive/critical care nephrology
- Multisystem and autoimmune diseases eg SLE and systemic vasculitis
- Renal stone disease
- Renal transplantation
- Renovascular disease
- Uro-nephrology

→ For more information, please contact Beverley Pell, Practice Manager, on 020 7224 5234 or at b.pell@thelondonclinic.co.uk

New consultants

April – June 2011

Anaesthetics

Dr Ian Appleby
MBBS FRCA
Consultant Anaesthetist
T: 020 7829 8711
E: applebyian@hotmail.com

Dr Susan Margaret Bailey
MBBS FRCA
Consultant Anaesthetist
T: 01372 735 270
E: susietoo@btinternet.com

Dr Colum Joseph Irving
MBBCh BAO FRCA
Consultant Anaesthetist
T: 020 7352 8171 x1748, x2727
E: colm.irving@rmh.nhs.uk

Dr Rajesh Mehta
MBBS BSC FRCA
Consultant Anaesthetist
E: rmehta0511@hotmail.com

Dr Alastair James Mulcahy
MBBS FRCA FFPMRCA
Consultant Anaesthetist
E: ajmulcahy@hotmail.com

Dr Jonathan Read
MBBS FRCA
Consultant Anaesthetist
T: 020 7794 050
E: jonread@me.com

Colorectal Surgery

Mr James Crosbie
MBBCh BAO LRCPs LRCPI MD FRCS
Consultant Colorectal Surgeon
T: 0845 155 5000 x3059
E: j.crosbie100@btinternet.com

Gastroenterology

Dr Gavin Johnson
MBBS MD MRCP
Consultant Gastroenterologist
E: gavin.johnson@uclh.nhs.uk,

Dr Patrick Kennedy
MBBCh BAO MRCP
Consultant Gastroenterologist
T: 020 7377 7338
E: p.kennedy@qmul.ac.uk

Dr Shahid A Khan
BSC MBBS PhD FRCP
Consultant Gastroenterologist
T: 020 7886 6666
E: shahid.khan@imperial.ac.uk

General Surgery

Dr Andrew Jenkinson
MBBS FRCS MS
Consultant General Surgeon
T: 07540 664 066

Neurology

Mr Suzanne O'Sullivan
BA MBBCh BAO MRCP
Consultant Neurologist
T: 07966 739 089
E: drsosullivan@aol.com

Oncology

Professor Michael Brada
MBChB BSC MRCP FRCP FRCR
Consultant in Clinical Oncology
T: 020 8661 3283
E: michael.brada@icr.ac.uk

Paediatrics

Dr Andrew Sawczenko
BM MRCP MRCPCh
Consultant Paediatrician
T: 020 7034 8950
E: dr.sawczenko@docrts.org.uk

Radiology

Dr Tara Barwick
MBChB MRCP FRCR MSC
Consultant Radiologist
E: tara@bareick.eu

Dr Thillainayagam Muthukumar

BM MRCP MRCPCh
Consultant Radiologist
T: 020 8909 5443
E: t.muthukumar@nhs.net

Rheumatology

Dr Yasser El Miedany
MDRhem FRCPC
Consultant Rheumatologist
T: 07545 295 787
E: yasser_elmiedany@yahoo.com

Clinic organises first Gulf Embassies football tournament

The London Clinic organised the first Embassy Football Tournament for Gulf Students on Saturday 14 May at Little Venice Sport Centre.

We have long been associated with the provision of internationally renowned medical expertise and clinical excellence for our patients both at home and abroad. We offer bespoke and specialist services to visiting nationals from well over 30 countries, through our dedicated International Office. Indeed, last month the Clinic was granted the Queen's Award for Enterprise in the International Trade Category as a result of successfully increasing overseas income by more than £9m in the past three years, reflecting our commitment to investment into the needs of international patients.

In particular, we treat a large number of patients from the Middle East and have strong links with the Gulf Embassies. The students who took part in the tournament are from the Gulf region and have been sponsored by their embassies to study in the UK, to enhance their knowledge of the English language and culture. This event provided these students with the opportunity to socialise and enhance their team spirit whilst meeting others with similar interests and from similar backgrounds.

During the event, teams from Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Saudi Arabia, Cyprus and The London Clinic competed in five aside football games. The tournament was attended by the Oman Medical Attaché, the Cultural Office from Saudi Arabia and members of the Royal Family of Bahrain.



Top: Teams from Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Saudi Arabia, Cyprus and The London Clinic competed

Bottom Left: The winning team from Saudi Arabia are presented with a trophy from Sanjay Shah, Chief Financial Director

Bottom Right: Gulf embassy students from Bahrain and Saudi Arabia take part

At the award ceremony that followed, the winning team from Saudi Arabia was presented with a trophy by Mr Sanjay Shah, Chief Financial Officer at The London Clinic.

Mr Shah said: "Whilst these elite and dedicated students are here studying, we believe it is important to enrich their experience as much as possible, and provide them with the opportunity to meet and socialise with others. We were delighted to play host to a number of key figures from the Gulf Embassies and the football tournament was a huge success and a day enjoyed by all who took part. The London Clinic boasts excellent relationships with Embassies and health offices in London and overseas and this event will further strengthen these international ties."

“ The London Clinic boasts excellent relationships with Embassies and health offices in London and overseas and this event will further strengthen these international ties.”

Mr Sanjay Shah,
Chief Financial Officer
The London Clinic



Editor:
Candy Jarvis,
Marketing and PR Executive

→ Your Feedback

If there are any topics that you would like to appear in future issues of the Notes, please send your suggestions to info@thelondonclinic.co.uk

