

RFreeNET News

Issue 3

The Neuroendocrine Tumour Unit

ENETS Centre of Excellence



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www.royalfree.nhs.uk/services/services-a-z/neuroendocrine-tumour-net-unit

Clinical Trials

Welcome everyone to our next instalment of RFreeNET News, where we have much to update you all on. To start off, we would like to take you through all the clinical trials that are currently available for patients under the care of the Neuroendocrine Tumour Unit. We have a fantastic team of nurses involved with clinical trials, led here in NET by our lead Research Nurse, Melissa Back.

If you have any questions, or would like to express an interest in taking part in any of the trials, please contact Melissa via her email melissa.back@nhs.net.

REMINET

Status: Open to recruitment

A European, multicentre, phase II/III randomised double-blind, placebo controlled study evaluating Lanreotide as maintenance therapy in patients with non-resectable duodeno-pancreatic neuroendocrine tumours after first-line treatment.

INCLUSION CRITERIA:

- Metastatic, non-resectable
- Well-differentiated duodeno-pancreatic NET
- Grade 1 or 2 / Ki-67 \leq 20%
- Progressive disease before first-line treatment.
- Stable disease after first-line treatment, within 4 weeks (28 days) prior to randomisation.
- Non-functional tumour

EXCLUSION CRITERIA:

- Grade 3 /Ki-67 > 20%.
- Pre-treatment by somatostatin long-acting analogue.

IMMUNET

Status: Open to Recruitment

Systematic Evaluation of the Immune Environment of Neuroendocrine Tumours.

Inclusion Criteria

- Life expectancy \geq 12 weeks
- Clinical indication for commencing systemic therapy as assessed by local medical team

Exclusion Criteria

- Past medical history of autoimmune disease.
- Other concomitant anti-cancer therapy except somatostatin analogues.
- Participation in other clinical trials.
- Patients who have received any form of irradiation to intended site of surgery/biopsy.
- No other previous treatment for NET permitted (except for somatostatin analogues)

CALMNET

Status: Open to recruitment

A Phase IV, Multicentre, Open label, Single Group Exploratory Study to Assess the Clinical Value of Enumeration of Circulating Tumour Cells (CTCS) to Predict Clinical Symptomatic Response and Progression Free Survival in Patients receiving Deep Subcutaneous Administration of Somatuline® (lanreotide) Autogel® to treat the Symptoms of Functioning Midgut NeuroEndocrine Tumours (NET).

INCLUSION CRITERIA:

- Diarrhoea and/or flushing at the time of study enrolment.
- Any NET
- Well/moderately differentiated NETs
- Ki67 <20%
- In need of somatostatin analogue.
- Positive octreoscan/ Gallium 68.

EXCLUSION CRITERIA:

- Treatment with unlicensed drug within the last 30 days before study entry or will require concurrent treatment with any other experimental drugs or treatments.
- Somatostatin analogues prior to study entry (unless a washout period)
- Interferon/chemotherapy/chemoembolization/radionuclide therapy within 3 months prior to study entry.

FETONET

Status: Open to recruitment

Evaluation of [18F]fluoroethyltriazole[Tyr3]Octreotate analogues for the imaging of neuroendocrine tumours. (FETONET) Phase 1.

INCLUSION CRITERIA:

- Any NET
- Metastatic disease.
- Octreoscan/Gallium 68 within 6 months.
- Measurable disease
- Life expectancy > 3 months.

EXCLUSION CRITERIA:

- Chemotherapy within 3 weeks of study
- radiotherapy (PRRT) within 4 weeks of study.
- Uncontrolled infections
- Patients receiving warfarin.

CLARINET FORTE

Status: Open to recruitment

Efficacy and safety of LANREOTIDE AUTOGEL® 120 MG administered every 14 days in well differentiated, metastatic or locally advanced, unresectable Pancreatic or Midgut Neuroendocrine tumours having progressed radiologically while previously treated with LANREOTIDE AUTOGEL® 120 MG administered every 28 days.

INCLUSION CRITERIA:

- well differentiated pancreatic or midgut NETs
- Grade 1 or 2
- Metastatic or locally advanced
- Functional or non-functional
- Ki67 \leq 20%.
- Positive PET scan in the organs of target lesions.
- Progression of disease while receiving first line treatment with lanreotide Autogel® at a standard dose of 120 mg every 28 days for at least 24 weeks (6 injections).

EXCLUSION CRITERIA:

- Grade 3
- VIPoma, Insulinoma, hindgut or foregut NETs, unknown primaries (except pancreatic)
- Multiple endocrine neoplasm
- Progressive disease during somatostatin analogue treatment

Trials in set-up

SPINET

A Phase 3, Prospective, randomised, double-Blind, multi-centre, study of the efficacy and safety of Lanreotide Autogel/depot 120mg plus BSC vs. Placebo plus BSC for tumour control in subjects with well differentiated, metastatic and/or unresectable typical or atypical lung Neuroendocrine tumours.

SEQTOR

Randomised open label study to compare the efficacy and safety of everolimus followed by chemotherapy with STZ-5FH upon progression or the reverse sequence, chemotherapy with STZ5FU followed by everolimus upon progression, in advance progressive pNETs.

OPS-C001

An international multi-center, open-label study to evaluate safety, tolerability, biodistribution, dosimetry and preliminary efficacy of ¹⁷⁷Lu-OPS201 for the therapy of somatostatin receptorpositive gastroenteropancreatic neuroendocrine tumors (GEP NETs)

NODAGA JR11

Quantification of somatostatin receptor subtype 2 expression in patients with bronchopulmonary and mediastinal neuroendocrine neoplasia using radiolabelled somatostatin receptor antagonists (NODAGA-JR11) PET/CT

COMPETE

A prospective, randomised, Controlled, Open-label, Multicentre phase III study to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with ¹⁷⁷Lu-Edotreotide compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR+), neuroendocrine tumours of gastrointestinal or pancreatic origin (GEP-NET).

NET Fundraising

London Marathon

Rob Borthwick (on the left), the son of one of our NET patients under the care of the Royal Free NET Unit (on the right) ran the London Marathon back in April, raising over £2500 towards NET research. A fantastic effort! You can read the full story on their just giving page:



£2,510.00

raised by 78 supporters

Donate

Share on Facebook

www.justgiving.com/fundraising/Rob-Borthwick



A special thanks to Noreen O'Sullivan, her family and friends. Her efforts raised nearly £30000 during an event at the Claddagh Ring. With an original target of £5000, Noreen organised a fundraiser at the Claddagh Ring in Hendon, with a disco, buffet, raffle and auction. The organisers said, "as a family who have experienced the benefits of the outstanding research and treatment provided by the Quiet Cancer Appeal first hand, we arranged a fundraising event to contribute back."

You can read the full story on their just giving page:
www.justgiving.com/fundraising/tqcfundraiser

If you are a NET patient or carer and would like to get involved with the Neuroendocrine Tumour Unit, please do not hesitate to contact us. We want to understand your needs beyond your medical treatment. Your views in research and your experience at the Royal Free are hugely valuable to us.

We would like you to help us design new research projects, help in fundraising events to keep the patient support group running, and NET research. Furthermore, your interaction will help collectively raise your voice and enhance your influence in defining policy.

If you would like to share your story with us and your fellow NET patients, please do not hesitate to contact us by email: jorge.garcia-hernandez@nhs.net or michaelwright2@nhs.net

Finally, Mike and Jorge are running in an Olympic Triathlon on the 6th of August. All the money raised is going towards the Quiet cancer appeal to support NET research. You can support us by following this link:

www.justgiving.com/fundraising/NET-PSG



Our fund is in collaboration with the Royal Free Charity, of whom we have a very close working relationship with. Our fund is named:

“The Quiet Cancer Appeal, Fund 311”

The name is very appropriate as most neuroendocrine tumours tend to be silent for many years. If you would like to make a donation to the NET Unit, please get in touch with our fundraising manager:

Diane Ryan

020 7472 6761 ext 34582

diane.ryan1@nhs.net



The Quiet Cancer Appeal at the Royal Free raise funds for research, led by Professor Martyn Caplin, into treatment for Neuroendocrine Tumours (NETs). NETs are a rare form of cancer that are hard to detect, hence the term ‘Quiet Cancer.’ Despite this, NETs are now one of the top five more common cancers in the UK and twice as common as pancreatic cancer, affecting men and women of all ages.

The Royal Free Hospital is a leading international centre for both treatment and research into NETs. Their research encapsulates studies into: genetics; detection of relapse; scanning agents. In order to guarantee the fantastic work that the *Quiet Cancer Appeal* undertakes – and to secure research to benefit future generations of rare cancer sufferers - they will need to raise £3million over 10 years.

Patient Research Ambassador Initiative

An initiative launched by the National Institute of Health Research (NIHR), its aim is to enhance the involvement of patients in research, not only as a participant but with the potential of influencing future research by collectively and formally raising their views.

What is a Patient Research Ambassador: PRA?

A Patient Research Ambassador is someone who promotes health research from a patient point of view. They could be a patient, service user, carer or lay person who is enthusiastic about health research and willing to communicate that to other patients and public as well as healthcare professionals. For further background on the history of **PRA's**, please click on the background page

Why do we need Patient Research Ambassadors: PRAs?

We want to embed a patient-centred research culture in the NHS. To do this, we need to engage both patients and NHS research staff. Patients, carers and lay people who have experienced research can often be the best 'Research Ambassador' in their local NHS care organisation. They can help ensure that people using local NHS care have the best opportunities and choices about taking part in research studies

What does the role involve?

Each Patient Research Ambassador will contribute according to their skills and interests and the time that they have available. There are broadly two types of Patient Research Ambassador. Those with a passion for research:

- **In a specific condition like neuroendocrine tumours**, where they have experience as a patient or carer. They may work with a particular department in a hospital Trust to inform more patients about research into the condition for example.
- **In general**. They may gain an overview of how the NHS care organisation makes its research available to patients as potential participants. They will then work with staff to identify where improvements can be made. They may also assist by talking to other organisational staff and patients to support these improvements.

What might Patient Research Ambassadors be doing?

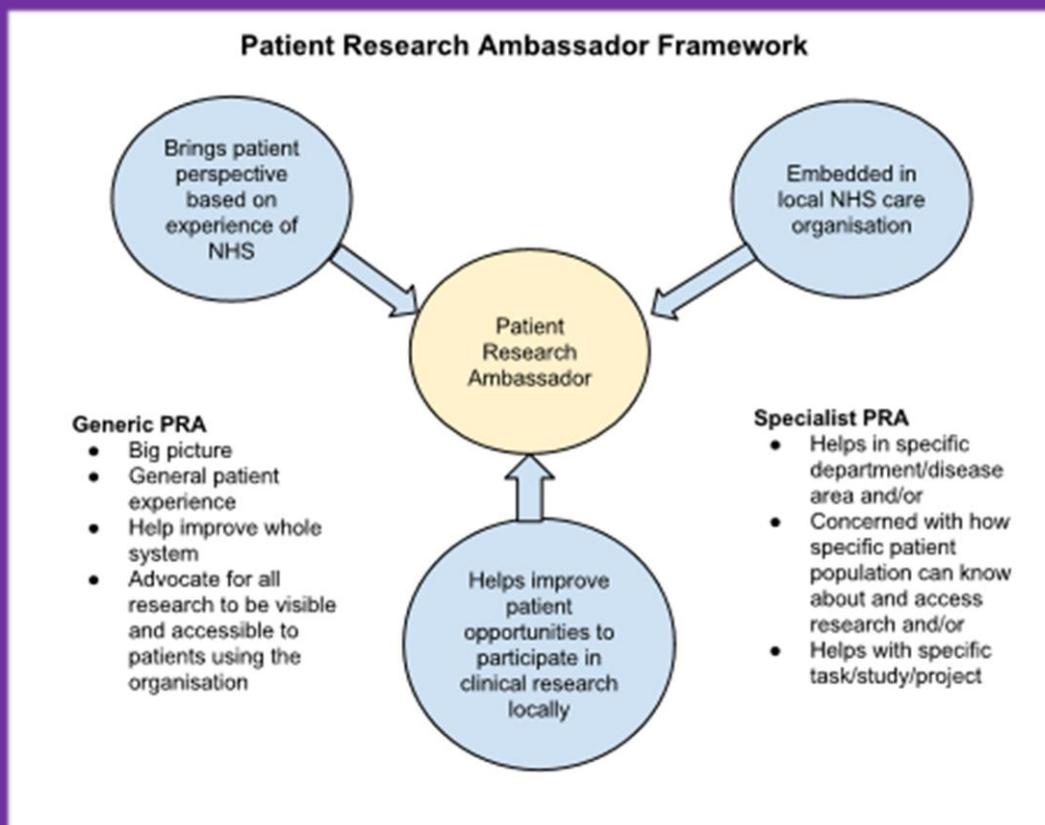
They could help an NHS care organisation become more research active through any one or a range of the following examples:

- Championing local public access to research e.g. through checking how the organisation makes known its research activity to patients and the public
- Helping to improve the awareness of staff and patients – from improving signs and advertising through to helping in staff training
- Being involved locally to support national initiatives.
- Helping medical researchers to develop patient orientated research proposals
- Helping to write patient friendly information about research

Aren't some of us already 'Patient Research Ambassadors'?

We recognise that there are many patients, carers and lay people already doing excellent work in the healthcare research world who might already describe themselves as 'patient research ambassadors'. In order to help create a focus on improving how patients can get access to healthcare research as potential participants and increasing choice for all patients and carers using their local NHS, we want to describe and widely promote a particular role in NHS care organisations that patients, carers and lay people who have been involved in research might choose to fulfil to help make this happen.

We have named this role Patient Research Ambassador. This is not meant to replace anything anybody is already doing in involvement in research. In some cases the local Patient Research Ambassador role might be an extension or natural development of what some people are already doing. Or it may already be being done under a different name. We want the Patient Research Ambassador role to compliment and be complemented by other activities which help deliver good relevant research for the benefit of NHS patients.



If you wish to register your interest you could follow this link and fill the registration form for this initiative:

<https://sites.google.com/a/nih.ac.uk/patient-research-ambassador-initiative/home/register-of-organisations-hosting-pras>

For further information of this topic you can find it here:

<https://sites.google.com/a/nih.ac.uk/patient-research-ambassador-initiative/home/learning-and-support/patient-research-ambassadors>

NET Diet Advice

Yasmin Chotai De Lima is our new Oncology and Neuroendocrine Dietician. Some of you might have met her. For those of you who haven't, we would like to introduce her to you.



During the last patient meeting some of you submitted dietary questions. Yasmin, very kindly has answered some of them. We would like this to be a regular section in the newsletter so feel free to send us questions for our dietician in forthcoming issues at jorge.garcia-hernandez@nhs.net

Do I need pancreatic enzymes supplements?

The pancreas produces enzymes that help the digestion of food. This includes digestion of fat, protein and carbohydrate. If your pancreas is not able to produce or release enzymes sufficiently you may not be getting all the nutrients out of the foods you are eating.

There are a few reasons why someone with a NET would require pancreatic enzymes, these include:

- Being on a somatostatin analogue. This is because somatostatin analogues reduce pancreatic enzyme release
- Having surgery where part of the pancreas (especially the head area), or the entire pancreas has been removed
- Having a tumour in the pancreas that is affecting its ability to produce or release pancreatic enzymes.

There are a number of different brands and strengths of enzymes so if one product does not help, it may be worth trying another. It is also important you take them correctly to obtain the benefits. Talk to someone from the NET team if you are unsure.

Dairy - Is it good or bad for me?

Dairy includes cow's milk, yoghurt, kefir, buttermilk, sour cream, butter, cheese, ice cream and cream. Dairy can be a good source of protein, vitamins and minerals (especially calcium). However dairy foods may also be high in fat (such as butter, ice cream and full fat milk).

Low fat dairy products should be included in a healthy diet to ensure you are getting enough calcium for bone health.

If you are losing weight, dairy can be a good way to add additional calories to your diet to help to stabilise your weight or even gain weight.

If you chose to avoid dairy, ensure you choose calcium enriched alternatives.

I want to put on weight but fat increases my diarrhoea. What can I do?"

Fat in the stools is called steatorrhea. This can be identified if your stools are pale, greasy/oily, offensive smelling, frothy, and/or floating. If you are experiencing steatorrhea, your body is not absorbing fats properly.

Depending on the cause, your doctor can prescribe medications that will help, such as pancreatic enzymes. They may decide to carry out a few tests to identify the cause. If you are on pancreatic enzymes already, you might need to review when and how much you are taking. Fat is a good source of calories to help put weight on, so don't reduce your fat intake without discussing it with a dietitian.



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Royal Free London
NHS Foundation Trust

NET PATIENT LED SUPPORT GROUP

9th September 2016

Atrium (Ground Floor) @ Royal Free

16:30 – 19:30

**For further information please
contact Jorge or Mike:**

jorge.garcia-hernandez@nhs.net

michaelwright2@nhs.net

020 7830 2867

QUARTERLY MEETINGS

FOR PATIENTS

AND CARERS

SHARED EXPERIENCES

NET RELATED
DISCUSSIONS

WELFARE AND
BENEFITS ADVICE

TRAVEL INSURANCE

RESEARCH
INVOLVEMENT

NET NEWSLETTER

FUNDRAISING

16:30 **Tea and Coffee**

17:00 **Advances and update in the diagnosis and treatment in Neuroendocrine tumours.**

Dr Christos Toumpanakis
Consultant in Neuroendocrine Tumours

17:40 **Questions and answers**

18:10 **Coffee break**

18:30 **Clinical Trials update**

Mr Jorge Garcia – Hernandez
Research Associate

18:40 **Questions and answers**

18:55 **Upcoming events & open forum discussion**

19:30 **End of meeting**

We are very pleased to present another edition of RFreeNET News. These are critical times for pushing forward the ambitions for our NET patients. We have increasing evidence for the benefit of a variety of drugs from clinical trials and it is so very important that the regulatory authorities especially NICE approve these drugs. Top of the agenda as many of you are aware is peptide radio-receptor targeted therapy (PRRT) with Lutetium-177 DOTA Octreotate which the Cancer Drugs Fund had removed, as well as other drugs including everolimus with the recent evidence of benefit in intestinal and lung NETs. NICE is however also reviewing the role of sunitinib in pancreatic NETs as well as Lanreotide for its anti-tumour effects and it is important that NICE is aware of the benefits. Your letters on how drugs have helped you are powerful tools in the argument.

Here at the Royal Free and across University College London, especially the Cancer Institute, the research programme continues to expand and thrive. Prof Tim Meyer's group are looking at circulating tumour cells from the blood stream as prognostic markers and looking to isolate DNA from these cells to do further genomic analysis and also see if ultimately we can predict which treatments would work best. Tim's group are also assessing how possible new therapies e.g. immunotherapies could be applied to NET patients and his team's research is looking at how one can predict the best responders to immunotherapy. Dr Christina Thirlwell's research team are continuing their work on the genomic understanding and the importance of epigenomics and how environmental factors and external influences can affect the chemicals which control the DNA and genetic changes. In addition Dr Christos Toumpanakis continues his team's work looking at prognostic factors assessing radiology, nuclear medicine and blood markers and we are opening up new areas of research to investigate the desmoplasia (scar/fibrotic tissue) and how we can look to treat this. I am also excited about the development for early 2017 to be looking at a whole programme into nutritional markers and new assays for measuring vitamins as well as for example 5HIAA using a simple blood test rather than a 24 hour urine collection. We also have expanding dietetic studies with Tara Whyand as well as Yasmin Chotai De Lima in regards of special diets eg. FODMAP and looking at other nutritional markers. We will soon be starting new nuclear medicine imaging studies in lung NET and also a new PRRT trial with a new drug which binds with even higher affinity (stickiness) to tumour cells. We thank you for your generous donations to our research fund RF Fund 311, it makes a big difference enabling continued growth of our research programme.

BREXIT could have an impact on some of our European collaborations and we will have to see how this evolves. I was leading a European Parliamentary application on Neuroendocrine Tumour care and it will be difficult for me to continue chairing such a group, coming from the UK, if we are leaving the EU! Whatever I will continue to advocate for what is right for NET patients across Europe. The European Neuroendocrine Tumour Society itself will not be affected by BREXIT. I am however confident about the future and the advances we can make for our patients.

We are desperately trying to improve our clinic space and look at clinic timing to reduce patient wait times. Please continue to provide feedback on our services as we continue to look to improve all areas of care. Please also continue to support the Royal Free Hospital Patient Support Group and of course our clinical trials.

Best wishes,



Professor Martyn Caplin