Welcome to the eighth edition of the FIAT Trial Newsletter

GOODBYE HOLIDAYS, HELLO WORK

With the summer holidays now a happy memory and the kids back at school, it’s time for everybody to get their heads down and focus on work again!

INSIDE THIS ISSUE

• Welcome from the FIAT CI Prof David Jayne
• Recruitment Update
• Top Recruiter
• German fistula plug trial
• Screening logs
• Objectives
• Reminder of Key Inclusion/Exclusion Criteria
• Amendments
• New member of the team
• Upcoming meetings…….. and much much more

Hello and Welcome from the FIAT Trial Chief Investigator, Professor David Jayne

Welcome to the September FIAT newsletter, which is packed with useful facts and figures about the trial. Thanks to all your efforts, we continue to make steady progress and are very close to reaching the landmark recruitment point of 200 patients. Although this is still somewhat off our original target we are greatly encouraged by the continued support the trial is receiving and in particular the number of new centres that have joined the study and added to the total; this is making a real difference. Despite innovation in the area, fistula-in-ano remains a highly controversial topic, with no one intervention having clear superiority. This is what makes the FIAT trial so exciting and so important - we still don’t know the best way to treat complex fistula-in-ano and where in the treatment algorithm the fistula plug sits. With a little extra effort to boost recruitment we will be in a position to answer these, and other, questions and so spare future patients the misery of living with chronic perianal sepsis.

Please continue the hard work to enable FIAT to do this.

Best Wishes
David Jayne

Page 1
Thank you all so much for your efforts recruiting patients into this important trial. FIAT has steadily continued to recruit patients over the last few months and to date 197 patients have been randomised.

We are really pleased by the progress in FIAT and the enthusiasm you have all shown for the study. However, we would like to increase recruitment over the coming months.

If there is anything we can do to help recruitment at your site, please get in touch with us and we would be pleased to help you.

A special mention to the following sites who have all randomised their 1st patient:

- Churchill/John Radcliffe Hospital (Oxford) Mr Chris Cunningham and team (Date randomised: 12-Jun-2014)
- Broomfield Hospital Mr Toby Hammond and team (Date randomised: 19-Jun-2014)
- Homerton Hospital Miss Tamzin Cuming and team (Date randomised: 15-Sep-2013)

The Big Question:
Who will randomise the 200th patient?
All will be revealed in the 200th patient celebratory edition of the FIAT newsletter.
Top three recruiters with regards to number of patients randomised:

FIRST PLACE:
St James's University Hospital
22 Patients

SECOND PLACE:
Sandwell General Hospital & Southend University Hospital
16 Patients

THIRD PLACE:
Queen Alexandra Hospital, Portsmouth
14 Patients

Top three recruiters with regards to average monthly recruitment:

FIRST PLACE:
Queens Hospital Burton
0.64 Patients per month

SECOND PLACE:
Southend University Hospital
0.57 Patients per month

THIRD PLACE:
Musgrove Park Hospital
0.50 Patients per month

Well done to all sites that have successfully randomised a patient into FIAT and thank you all for your hard work and continued support!

Table of top 5 recruiting centres by average number of patients recruited per month.

<table>
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<th></th>
<th>SITE</th>
<th>DATE OPENED</th>
<th>NUMBER OF MONTHS OPEN</th>
<th>NUMBER OF PATIENTS RECRUITED</th>
<th>AVERAGE NUMBER OF PATIENTS RECRUITED PER MONTH</th>
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<td>Musgrove Park Hospital</td>
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<tr>
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<td>Sandwell General Hospital</td>
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Initial results from the German multicentre fistula plug RCT

The preliminary results from the German multicenter trial comparing the COOK fistula plug with the rectal advancement flap have recently been reported in abstract format. Eighty-two patients with cryptoglandular fistulae were randomised to either treatment with fistula healing determined by closure of the external opening and the absence of pain or drainage. At 1-year post follow-up there was no significant difference in healing rates: fistula plug 67% versus advancement flap 76% p=0.59. Importantly, there was more incontinence to solid stool in the advancement flap group when compared to baseline, a difference not observed with the fistula plug. Operation time was significantly shorter in the fistula plug group.

These results are in keeping with the 50-60% healing rate reported with the fistula plug in the literature and support the use of the fistula plug as a sphincter preserving option in complex fistulous disease.
They underline the importance of the FIAT trial in providing rigorous assessment of treatment options for fistula-in-ano, with quality control provided by baseline and follow-up MRI studies.

LOOK OUT!

High Transphincteric Fistula??

Look out for patients with a confirmed high transphincteric fistula at risk of incontinence with fistulotomy (involving approximately 1/3 or more of the external sphincter complex).

Within FIAT a high fistula is defined as one that on clinical grounds runs a significant risk of incontinence, if treated with fistulotomy (i.e. potentially involves a significant portion of the external sphincter complex.)

Screening Logs

On a monthly basis the FIAT Trial office sends out a request for a FIAT Trial screening log from all open sites. Can I please remind everyone to send their completed screening logs to the FIAT Study office when they receive the request.

Which patients should be included? The FIAT patient screening log should list all of those potentially eligible patients who have been screened for entry into the FIAT study – randomised or not, including those patients who have had a fistula plug inserted.

What information will be collected? Anonymised information only. Data collected will be: diagnosis, management plan and the reason excluded or if a patient is eligible and declines, reason they declined to participate.

Why? The data collected on the screening logs will help us identify any barriers to recruitment and ensure that the correct types of patients are being excluded.

How will the data be collected? The FIAT study office will contact each site once a month requesting data for those patients screened for entry into the FIAT Study – randomised or not. You should already have been sent the data collection forms, if not contact the FIAT study office.

The FIAT study office encourages that you nominate someone at site responsible for collation of this data.

2. EUA to characterise the nature of the fistula.

3. Fistula tract ≥ 2cm.

4. Single internal fistula opening present at EUA.

5. Draining seton insertion for a minimum 6 weeks prior to randomisation.

6. Baseline MRI scan within 6 months of randomisation.

7. Cryptoglandular aetiology.

8. Patients must be >18 and able to provide informed consent.

1. Low transphincteric fistula-in-ano.

2. Non-cryptoglandular fistulae.

3. Other perineal fistula.

4. Complex disease with >1 internal fistula opening present.

5. Clinical evidence of active perianal sepsis.

6. Patients with a recurrent anal fistulae previously treated with a plug.

7. Absolute contraindication to MRI.

8. Cultural or religious objection to the use of pig tissue.

9. Contraindication to general anaesthesia.

10. Unable/unwilling to provide informed consent.
Non-Substantial Amendment Number 4  
(Dated 7th April 2014)  
Patient Information Poster

We recently submitted a non-substantial amendment to gain approval for CRF’s used within FIAT. ‘Confidential once approved’ has been added to the footer of all CRF’s used within FIAT following an update to the University of Birmingham’s information and security policy which stipulates that all confidential data must be marked as such. Other minor changes have been made to the Randomisation Notepad, Baseline Data Form, Baseline Radiology Form and the Follow-up Radiology Form.

The Research Ethics Committee have reviewed this amendment and do not consider this to be a “substantial amendment”. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately. This is ready to be implemented at your site.

The lead CLRN (West Yorkshire CLRN) for the FIAT study has completed the global checks and notified all the NHS trusts participating in FIAT of this amendment. The CLRN has also confirmed that this amendment does not require review by individual NHS trusts and can be implemented immediately as we have all regulatory approvals in place.

Substantial Amendment Number 6  
(Dated 27th August 2013)  
Patient Information Poster

We have ethics approval to use a patient information poster. The aim of the poster is to raise awareness of the FIAT Study amongst the patient population. The poster contains a brief description of the study, how to get involved and what it means to be involved.

Please display the patient poster in clinics and patient waiting areas, where potential patients are likely to read the poster.

If you would like additional copies of the patient poster to be sent to you, please do not hesitate to contact the FIAT Study office.
We’re delighted to welcome Mrs Mandy Eyre to the FIAT team! Mandy is the new FIAT research nurse and is based at Queens Medical Centre with Professor John Scholefield.

Mandy began her nursing career in the Royal Air Force and served in the force for approximately 8 years; working mainly on a male surgical and orthopaedic ward. Following this Mandy took up a post at Hull Royal Infirmary, in their operating theatres as a scrub nurse, ‘Scrubbing’ for a wide variety of specialties and it is here where she got her first sample of colorectal surgery. Mandy then moved to Grantham and District Hospital where she became part of their operating team, specialising in colorectal surgery. Mandy has attended the Laparoscopic Colorectal Course at the Institute of Excellence in Hamburg.

Finally after many years of theatre nursing, Mandy decided it was time for a change in direction and chose to enter the career pathway of research nursing. Mandy is really enjoying her new role as FIAT research nurse and looks forward to the challenges and tasks that lie ahead.

For those of you who don’t already know me I am one of the FIAT research nurses based in Leeds with the Chief Investigator, Prof David Jayne. My primary role, and that of my new colleague Mandy Eyre, is one predominantly of support to all the nurses involved in FIAT. Most of you will have already had a site visit from me which I hope was helpful, for those sites that haven’t and think that this is something that would be beneficial, please feel free to drop me an email. Likewise if you are struggling to identify or recruit patients and feel that a follow-up visit or telephone call would be beneficial please get in touch directly or via BCTU.

Lastly, I am always contactable so if you have any questions no matter how simple please get in touch. My contact details are as follows: e-mail: catherine.moriarty@nhs.net office number: 0113 2064672, mobile: 07909 960597.

Whether you want one or need one....... you must have one

Site Visits

If you would like to arrange a site visit then please contact the FIAT Study office (FIAT@contact.bham.ac.uk) both Catherine and Mandy would be delighted to visit your hospital and discuss FIAT!
The date and time of the next FIAT Trial Nurses teleconference has been confirmed for Thursday 2nd October 2014 with a start time of 10:00am.

A great opportunity for the nurses to share experiences with other nurses working on the trial and discuss any problems/barriers to recruitment and possible ways to overcome these. If you would like to attend, but have yet to confirm your attendance, contact the FIAT study office: FIAT@contacts.bham.ac.uk

We hope you will find this a useful event and we look forward to talking to you soon!

We wish to make you aware that the coordinating trials unit for the FIAT Trial, Birmingham Clinical Trials Unit, has moved location. As of Friday 18th July 2014, BCTU has moved to the address on the right:

Please use the new address from now on for all correspondence.

We will be informed of any post that is misdirected to our old address so vital post should not go missing.

NEW ADDRESS:
Birmingham Clinical Trials Unit (BCTU)
School of Health & Population Sciences
College of Medical and Dental Sciences
Public Health Building
University of Birmingham
Edgbaston
Birmingham
B15 2TT

For further information about FIAT please contact the FIAT team at:
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E-mail: p.antonio@bham.ac.uk Tel: 0121 415 9104
FIAT Trial Nurse: Ms Catherine Moriarty
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The FIAT TMG would like to thank all the FIAT trial Collaborators for supporting the FIAT Study.

We hope you found this newsletter interesting and informative.

If you have any trial or recruitment issues that you would like to tell us about - that you think may be of interest to other sites, please email us at FIAT@contacts.bham.ac.uk and we will add it to the next newsletter.

If you would like to contribute to the next newsletter - whether by suggesting ways it could be improved or writing about your own experiences - please get in touch using the details above.

We’d be happy to hear your comments or any ideas for anything you’d like to see in the next issue.