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If you have a query please contact one of the team:



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MifeMiso Trial



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MifeMiso reaches pilot phase recruitment target!



Seasons greetings and welcome to the second edition of the MifeMiso newsletter! We're delighted to announce that we have already hit our pilot phase recruitment target which is to have 60 women recruited by the end of February 2018. We have also recently passed the 10% mark and currently have 73 women recruited in total up to 20th December 2017.

This is a fantastic achievement

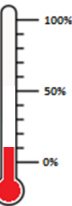
and we would like to say a huge thank you to all our recruiting sites for your hard work!

We would like to welcome new sites that have opened since the last newsletter: Birmingham Women's Hospital, Glasgow Royal Infirmary, West Middlesex University Hospital, Chelsea and Westminster Hospital, Birmingham Heartlands Hospital, Newham University Hospital and Princess

Royal Hospital (Telford). Very well done to teams at these sites who have recruited and a special congratulations to Birmingham Women's Hospital who are already our second best recruiter.

We wish everyone a very Merry Christmas and a Happy and Prosperous New Year!

10% of the way!
73 recruited/710 total target



Total recruited up to 20th December 2017

Total Recruited			
Position	Centre	Date activated	Total recruited
1	Sunderland Royal Hospital	25 September 2017	21
2	Birmingham Women's Hospital	17 November 2017	13
3	St Michael's University Hospital, Bristol	25 September 2017	7
4	University College London Hospital	27 September 2017	6
5	Whipps Cross University Hospital	02 October 2017	4
6	Liverpool Women's Hospital	09 October 2017	3
6	St Thomas' Hospital	02 October 2017	3
6	University Hospital Coventry	25 September 2017	3
9	West Middlesex University Hospital	29 November 2017	2
9	Chelsea and Westminster Hospital	29 November 2017	2
9	Princess Anne Hospital, Southampton	09 October 2017	2
9	Queen Alexandra Hospital, Portsmouth	20 September 2017	2
9	Queen's Medical Centre, Nottingham	20 September 2017	2
14	Queen Elizabeth University Hospital, Glasgow	25 October 2017	1
14	Royal Infirmary of Edinburgh	03 October 2017	1
14	Royal Victoria Infirmary, Newcastle	29 September 2017	1
17	Princess Royal Hospital, Telford	06 December 2017	0
17	Birmingham Heartlands Hospital	30 November 2017	0
17	Newham University Hospital	02 November 2017	0
17	Glasgow Royal Infirmary	26 October 2017	0
17	Royal London Hospital	11 October 2017	0

MifeMiso Meet Up - be sure to dial in!

The MifeMiso trial team will be hosting teleconferences starting in the new year. These will be open to all sites who are open to recruitment and those in set up to join and discuss recruitment issues, share best practice across sites and for the trial team to provide updates. The first teleconference will be held on **Monday 15th January 2018, 11:30am-12:30pm**. We have also scheduled the second teleconference for Tuesday 13th February 2018, 10-11am. If you haven't done so already we'd be grateful if you could respond to the calendar invites to confirm your availability and we look forward to speaking with you!



Reminder - BCTU Christmas Closure



Please note that BCTU will be closed from **approx. 12pm on Friday 22nd December 2017 and will re-open at 9am on Thursday 4th January 2018**. During this period the BCTU telephone randomisation service will be unavailable however the online randomisation system (www.medscinet.net/mifemiso) will continue to be available 24/7.

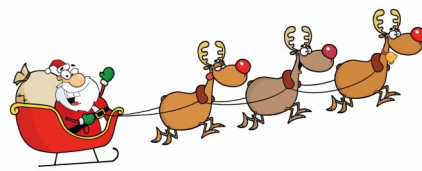
If you need to report an SAE during this period please continue to email reports to the MifeMiso NHS.net account (bwh-tr.mifemiso@nhs.net) or fax to 0121 415 9136 which will be checked

*“You
have to
be in it
to win
it!”*

Patients mean prizes!

Congratulations to the teams at **Sunderland Royal Hospital** and **Birmingham Women's Hospital** who won recruiter of the month for October and November 2017 respectively. Remember in order to be in with the chance of winning some limited edition MifeMiso merchandise your site just has to recruit at least one woman to MifeMiso for that particular month! Who will be the winner for December?!





Substantial amendment 3



We will be submitting a substantial amendment early in the new year. The main changes being included in this amendment are:

- **Satisfaction survey (CSQ-8 questionnaire)** - adding instructions for women to email a copy of their questionnaire to the MifeMiso NHS.net account in addition to posting (via freepost envelope) and obtaining permission to use an electronic version of the questionnaire (via smart survey)
- **Clinic poster**—creating a separate version of the poster without the wording ‘Have you been diagnosed with a missed miscarriage?’ and a version including the term ‘delayed’ as well as ‘missed’ (in response to feedback from sites)
- **Protocol**—adding sublingual route for administration of misoprostol, clarification that if a woman is scanned earlier than day 7 and if the sac has passed these women do not require another scan on day 7 and clarification of storage temperature for IMP

We will inform sites once the amendment has been submitted for REC and HRA review and has been categorised; in order for local R&Ds to begin their review

Reminders



* Pregnancy tests

We wish to clarify that even if a woman has surgical management before day 21 we would still like these women to conduct a pregnancy test. This is not only important to collect clinically but the pregnancy test result is a secondary trial outcome so it is very important that every effort is made to collect this information

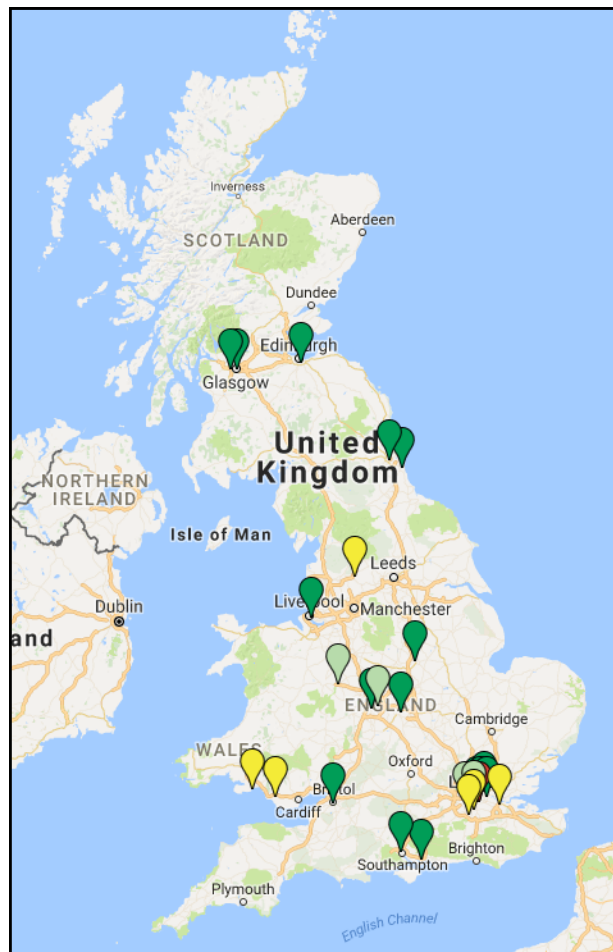
* Contraindications

Please remember that women are not eligible to be recruited for MifeMiso if they have any contraindications to either Mifepristone or Misoprostol. These include: chronic adrenal failure, known hypersensitivity to either drug, haemorrhagic disorders and anticoagulant therapy, prosthetic heart valve or history of endocarditis, existing cardiovascular disease, severe asthma uncontrolled by therapy or inherited porphyria

* Screening logs

Please only include women on the screening logs who have been diagnosed with a missed miscarriage and have opted for medical management but did not get recruited to the trial

MifeMiso sites



- First wave sites open
- First wave sites in set up
- Second wave sites open
- Second wave sites in set up



*Merry Christmas from the
MifeMiso trial team!*



- 1. Missed Miscarriage*
- 2. Medical Management*
- 3. Think MifeMiso!*



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