



**Contact us**

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



Leanne Beeson  
Trial Manager

E-mail: [mifemiso@trials.bham.ac.uk](mailto:mifemiso@trials.bham.ac.uk)  
Tel: 0121 414 9011



Dr Justin Chu  
National Clinical Coordinator  
E-mail: [justinchu@doctors.org.uk](mailto:justinchu@doctors.org.uk)  
Tel: 07810 350470



Dr Adam Devall  
Team Leader for Miscarriage Research  
E-mail: [a.j.devall@bham.ac.uk](mailto:a.j.devall@bham.ac.uk)  
Tel: 07971 823452



Mary Nulty  
Data Manager  
E-mail: [mifemiso@trials.bham.ac.uk](mailto:mifemiso@trials.bham.ac.uk)  
Tel: 0121 414 9011



# MifeMiso Trial

ISSUE 5

OCTOBER 2018

## MifeMiso recruitment exceeds 60% of target!

**60%**

Congratulations to sites that won a prize at the Collaborators meeting and well done and thank you all for your incredible efforts in reaching over 60% of the recruitment target!



62% of the way!

439 recruited/710 total target

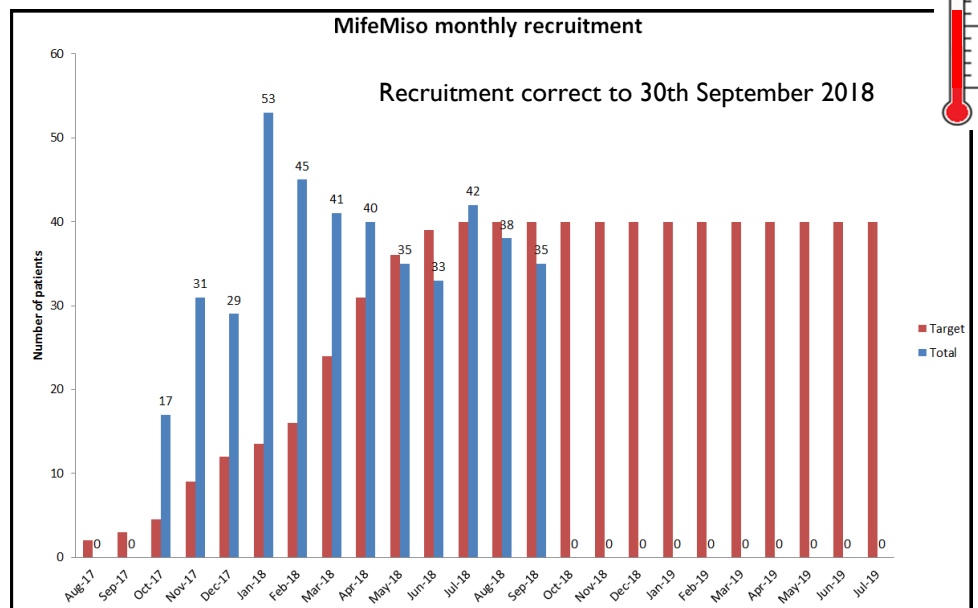
Hello, and welcome to the 5th edition of the MifeMiso newsletter! After a very hot summer, we have now truly entered the Autumn season, as the weather has cooled down. We are delighted to say that in July our recruitment surpassed the half way mark—congratulations again to the team at St Michael's Hospital, Bristol for recruiting the 355th participant!

early 2018 we're pleased to see recruitment picked up again over the summer period with an average of 40 women recruited in July and August. Please keep up the good work and remember to only recruit women who confirm, prior to randomisation, that they're definitely able to attend for a follow up ultrasound scan at day 6-7 post-randomisation.



After seeing a gradual decline in recruitment in

### Monthly recruitment against projections



# Collaborators meeting



Thank you to those who recently attended the MifeMiso Collaborators Meeting on 11th September 2018– it was great to see the majority of sites represented from delegates who attended. We hope attendees found the meeting useful and enjoyed the day. The **top 3 key messages** from the meeting were:

## **1. Day 6-7 ultrasound scan**

- ◆ Please ensure women return for their day 6-7 ultrasound scan (except for women who end up having surgical management prior to this time point or who have a scan earlier than day 6-7 and the sac has passed). **This is essential for the primary outcome data.** Please ensure only women who can confirm, prior to randomisation, that they are definitely able to attend the day 6-7 scan are randomised to the trial, and that there is a scan slot available and staff cover in place

## **2. Appointment reminders to women**

- ◆ We would appreciate it if research teams could contact women via telephone and/or text **48 hours** prior to their scan date (day 6-7) and prior to their day 21 follow up time point to remind them to attend for the scan and complete the pregnancy test. If the number you call on will be a withheld number, please make the women aware of this beforehand or un-withhold the number. For those who do not have access to a work mobile, potentially texts could be sent via NHS.net accounts. If you would like to send texts via this method we suggest contacting your IT department to see if this can be arranged.

## **3. Schedule for appointments/follow up time points**

- ◆ Please make sure women know their follow up dates for day 2, day 6-7 and day 21 (+/-2 days) in advance. Appointment dates can be noted on the reverse of the blue participant emergency contact cards. We will share trial stickers in due course which can be used for this purpose.



*Prof Arri Coomarasamy speaking about the Miscarriage care bundle*



*Discussions during the MifeMiso break out session*



Group photo, MifeMiso collaborators meeting, 11/09/2018

## Site prize winners



Congratulations to the following sites who were awarded prizes at the Collaborators meeting. We hope you enjoyed your chocolates!

**Top recruiters:** 1st prize - Sunderland Royal Hospital, 2nd prize - UCLH, 3rd prize - St Michael's Hospital, Bristol

**Best regional recruiting sites:** **Scotland** - Glasgow Royal Infirmary, **Wales** - Singleton Hospital, **North (England)** - Burnley General Hospital, **Midlands (England)** - Birmingham Women's Hospital, **London (England)** - West Middlesex University Hospital, **South (England) (outside of London)** - Queen Alexandra Hospital, Portsmouth

**Most number of women screened:** Birmingham Heartlands Hospital



Janet Scollen from Sunderland collecting 1st prize for top recruiting site

## Top trial tips



Three of our top recruiting sites share their top 3 MifeMiso tips:

\* **University College London Hospital:-**

- 1) Organise 'MifeMiso cup' for doctors to compete for prizes for 5, 10, 15, 20, to 50 recruits. Prizes can range from a pen or chocolates to dinner.
- 2) Having the P.I very involved in the study, and ensuring all doctors are signed onto the delegation log and trained on the study
- 3) Making the doctors on site aware of the point of contact for the study if they have a recruit and the back up person in their absence

\* **St Michael's University Hospital, Bristol:-**

- 1) The nurse practitioner mentions the trial to the patient when giving miscarriage options and mentions she can speak with the research nurse for more information. The RN is always based in EPAC
- 2) Informs the lady that on their day 6-7 scan the consultant P.I will undertake the scan with her. This is a selling point
- 3) They offer the lady an extra visit on day 21 to do the pregnancy test and discuss any concerns or questions she may have before final discharge, offering the patient extra support

\* **University Hospital Coventry:-**

- 1) Use an iPad to randomise the woman to save her from unnecessary journeys through the unit
- 2) Give the lady a pregnancy test when she undertakes her scan so she does not have to buy one
- 3) Note on the booking diary for EPAU that if a lady goes to book in a medical management then they consider MifeMiso



## Substantial amendment 4



The documentation for substantial amendment 4 was submitted to REC/HRA on 2nd October 2018 following approval from the sponsor. We have since received amendment acknowledgement from REC along with the HRA categorisation email which has confirmed the amendment is category A. We have supplied sites (including members of the research team, pharmacy team and R&D) with the amendment documentation for review. As stated by email, sites have 35 calendar days to review the amendment from the date of notification therefore if your site does not raise an objection to the amendment by **8th November 2018** we will assume the amendment may be implemented at your site once all regulatory approvals are in place. Once approvals have been issued from REC/HRA these will be forwarded to sites and we will send hard copies of the amendment paperwork to the main research nurse/ midwife at each site along with participant appointment schedule labels

## AEPU annual meeting

The trial team will be having a stand at the AEPU annual scientific meeting, 8-9th November 2018 in Sheffield. There is also a Research Network meeting arranged for 6:15-7:15pm on Thursday 8th November which we will be attending. We hope to see you there!



## MifeMiso Meet up, 27/11/2018

The next 'MifeMiso Meet Up' is scheduled for **Tuesday 27<sup>th</sup> November 2018, 11:30am-12:30pm**. Please RSVP if you would like to attend and haven't already let us know. We hope you can join us and we look forward to speaking with you

## IMP transfer between sites



The IMP stored by the manufacturer (ModePharma) has now all been distributed to recruiting sites. We are in the process of initiating IMP transfers between sites from sites that are likely to have a surplus of IMP left at the end of recruitment to those sites that require a further resupply. We will be in touch with further details if we're required to make an IMP transfer to/from your site



## Baby Loss Awareness Week

Baby Loss Awareness Week is 9-15th October 2018 which culminates with the global 'Wave of Light' event on 15th October which is also recognised as International Pregnancy and Infant Loss Remembrance Day. There are plenty of ways to get involved in raising awareness if you're interested. Please visit <https://babyloss-awareness.org/> for more information



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



Chief Investigator: Professor Arri Coomarasamy

Coordinating centre: Birmingham Clinical Trials Unit

Tel: 0121 414 9011

W: [medscinet.net/mifemiso](http://medscinet.net/mifemiso)

✉: [mifemiso@trials.bham.ac.uk](mailto:mifemiso@trials.bham.ac.uk)

🐦: @mifemiso\_trial