



Contact us

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



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MifeMiso Trial



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MifeMiso recruitment target reached!

Welcome to the eighth edition of the MifeMiso newsletter and we hope you've been enjoying the summer weather!

We're delighted to confirm that the MifeMiso recruitment target of 710 was reached on 22nd July 2019 with **UCLH** recruiting the 710th lady! Congratulations and well done to all our sites on such a fantastic effort to ensure the recruitment target was achieved ahead of time!

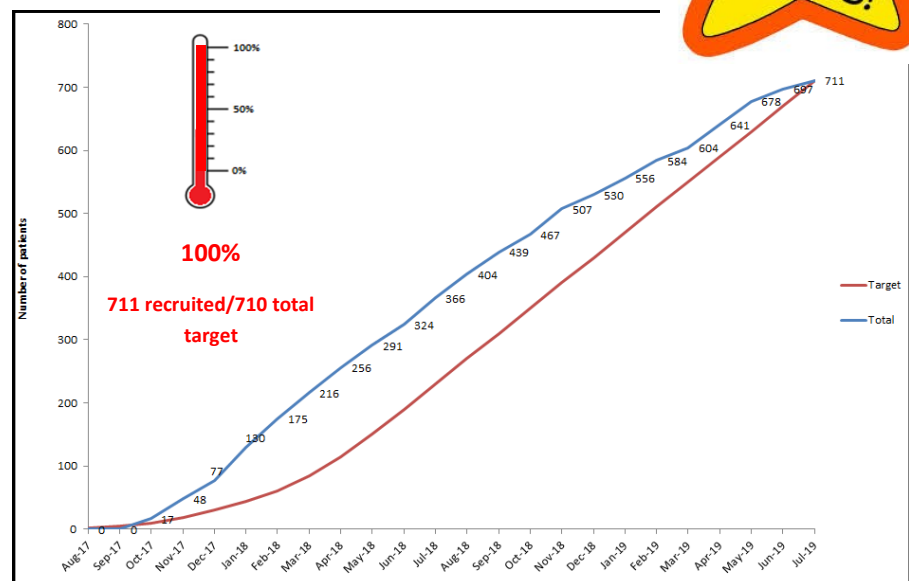
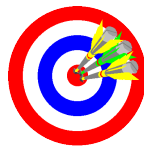
Following this, the trial formally closed to randomisation on 31st July 2019 with a total of 711 participants.

The priority now is to ensure all data entry and data queries are completed promptly in order for the database to be locked and the final analysis to be conducted. We would appreciate your cooperation in responding to any data queries in a timely manner.

Thank you all for your hard work and dedication in recruiting to this important trial and we look forward to sharing the results with you in 2020!



UCLH team with gift hamper prize for recruiting 710th MifeMiso lady



Recruitment league table - final figures



Centre	P.I	Activation date	Total recruitment
Sunderland Royal Hospital	Amna Ahmed	25 September 2017	108
University College London Hospital	Joel Naftalin	27 September 2017	60
West Middlesex University Hospital	Natalie Nunes	29 November 2017	59
St Michael's University Hospital	Abigail Oliver	25 September 2017	49
Queen Alexandra Hospital	Nime Vaithilingam	20 September 2017	47
University Hospital Coventry	Feras Izzat	25 September 2017	38
Singleton Hospital	Frances Hodge	11 January 2018	31
Burnley General Hospital	Kalsang Bhatia	05 April 2018	30
St Thomas' Hospital	Judith Hamilton	02 October 2017	28
Birmingham Women's Hospital	Yadava Jeve (previously Ismail Hassan)	17 November 2017	28
Southmead Hospital	Jane Mears	01 June 2018	25
Queen's Medical Centre, Nottingham	Shilpa Deb	20 September 2017	20
Liverpool Women's Hospital	Linda Watkins (previously Penny Robshaw)	09 October 2017	18
Chelsea and Westminster Hospital	Natalie Nunes	29 November 2017	18
Princess Royal Hospital, Telford	Martyn Underwood	06 December 2017	18
King's College Hospital	Jackie Ross	01 February 2018	18
Princess Anne Hospital, Southampton	Ying Cheong	09 October 2017	17
Glasgow Royal Infirmary	Chitra Kumar	26 October 2017	16
Queen Elizabeth University Hospital	Stewart Pringle	25 October 2017	13
Birmingham Heartlands Hospital	Pratima Gupta	30 November 2017	13
Royal Victoria Infirmary, Newcastle	Meena Choudhary	29 September 2017	12
St Helier Hospital	Sangeetha Devarajan	05 April 2018	12
Whipps Cross University Hospital	Anupama Shahid	02 October 2017	11
Royal Infirmary of Edinburgh	Andrew Horne	03 October 2017	11
Royal London Hospital	Anupama Shahid	11 October 2017	4
Epsom Hospital	Sangeetha Devarajan	08 May 2018	4
Princess of Wales Hospital	Frances Hodge	11 January 2018	2
Newham University Hospital	Anupama Shahid	02 November 2017	1

IMPORTANT NOTICE

Data queries and close down

Now that we have closed to randomisation it is vitally important that the focus is on completing follow up and resolving all data queries. We would appreciate your full cooperation with responding to data queries in a timely manner. This is extremely important so that in due course the database can be locked and the final analysis can be conducted.

Please ensure that you are regularly checking the 'monitoring' tab on the MifeMiso database for any queries raised. Once you have checked your queries please save your responses so these can be checked by the MifeMiso team. If you have any queries about this, please contact a member of the team.

Once the data set is finalised we will contact all site P.Is to request electronic sign off of e-CRFs for each individual participant. Again, we would appreciate the full cooperation of P.Is with this to ensure the sign off is done in a timely manner.

Pharmacy close down checklists have now been sent out to pharmacy teams and we would be grateful if completed checklists could be returned to mifemiso@trials.bham.ac.uk

ISF close down checklists will be circulated shortly. We would be grateful if completed checklists could be returned to mifemiso@trials.bham.ac.uk once all data queries have been resolved and the P.I has signed off e-CRFs for all participants via the database. Following this, we will confirm when your site is formally closed and therefore when trial documentation can be archived

Substantial amendment 5



Substantial amendment 5 has now been approved by REC and HRA and the deadline to review the amendment is **30th August 2019**. Please let us know if your site requires additional time to review the amendment, otherwise once the deadline date is reached we will assume the amendment may be implemented at your site if no objection has been raised or a request for more time hasn't been made.

Please send AM5 approvals/confirmation of continued capacity and capability, completed ISF/pharmacy version control checklists and P.I signature pages from protocol v5.0 to mifemiso@trials.bham.ac.uk

Reminder - Site invoices

Don't forget to invoice for your site payments! Invoices should be addressed to Leanne Beeson and emailed to mifemiso@trials.bham.ac.uk or posted to the MifeMiso Trial Office address. Payments include £150 for site file maintenance and archiving, £275 for pharmaceutical receipt and dispensing of IMP and £150 per patient recruited. In addition, wave 1 sites can invoice for 20% FTE research nurse support for 24 months



Recruitment data uploads

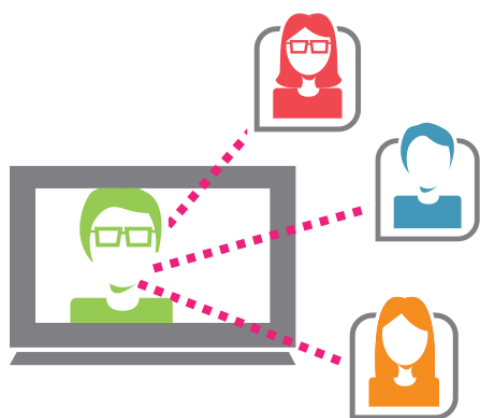


You may already be aware that the process has changed for uploading recruitment data. It is now a requirement for sites to upload recruitment data to EDGE rather than the central trial team uploading data to CPMS and this feeding through to EDGE. Please ensure your recruitment data is up-to-date and has been uploaded

Career break

MifeMiso Trial Manager, Leanne Beeson, will be taking a career break to go travelling from 4th November 2019 with an anticipated return date of mid-February 2020. During this time please continue to email mifemiso@trials.bham.ac.uk or call 0121 414 9011.

Queries will be dealt with by BCTU colleagues; Dr Hannah Noordali (Data Manager) and Dr Adam Devall (Team Leader)



Results reveal meeting

We will arrange a results reveal meeting via webinar to share the final results with all our sites when we're close to publication. Look out for further details in 2020 and we hope you can join us!

Happy Summer Holidays from the MifeMiso trial team!



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



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