

Issue 4
JUN 2026

ACESO Trial

Upadacitinib Co-therapy with Corticosteroids in Early Acute Severe Ulcerative Colitis
(A Phase III randomised placebo controlled double blinded trial)



This newsletter will provide you with the current study status, updates, tips and other useful information.

THANK YOU & WELL DONE

Thanks to all the participating sites for your valuable efforts and ongoing commitment in supporting the interim analysis database lock. Well done to everyone involved!

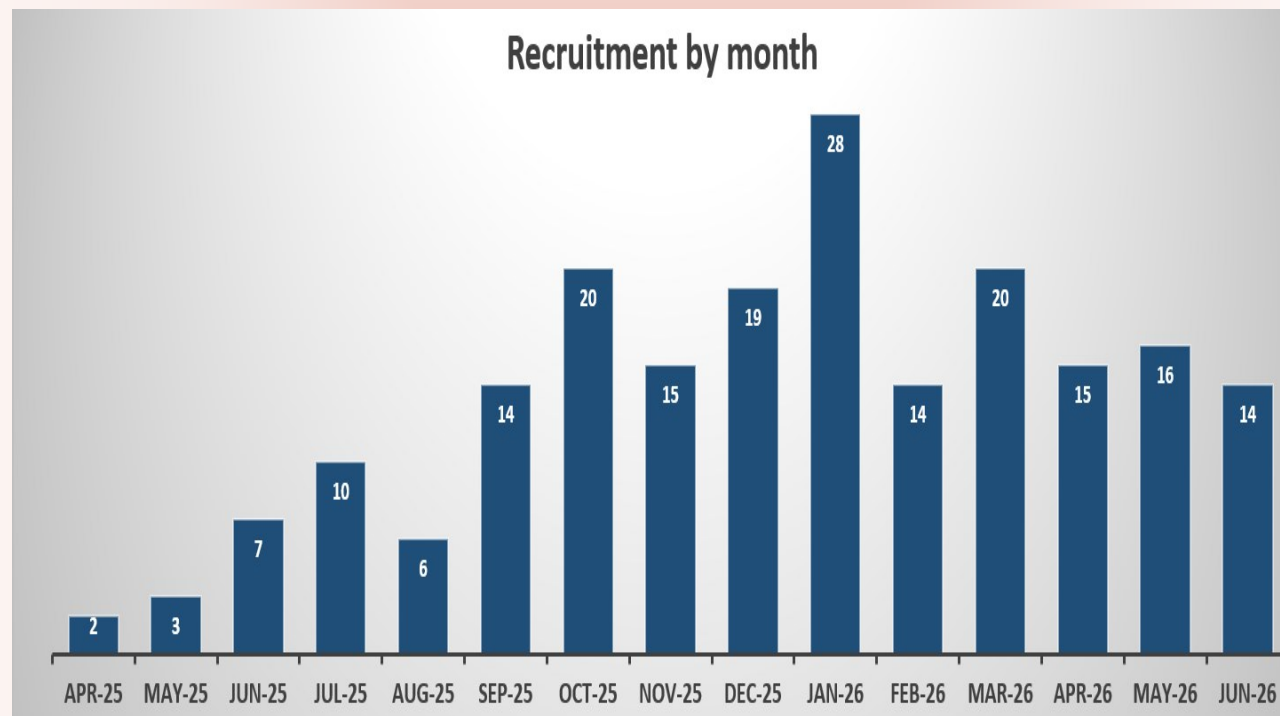


Special thanks to **Southampton** and **Cardiff** on achieving their first recruit. Congratulations as well to our top 5 sites including **Hull, Cambridge, St Georges, Wolverhampton & Imperial** for maintaining an impressive recruitment rate — fantastic work!

RECRUITMENT UPDATE

We are delighted to share that, as of 30 June 203 participants have been recruited.

😊 If there is anything we can do to support recruitment at your site, please let us know. Your continued efforts are greatly appreciated!





INFORM REMINDERS

Thank you for your continued collaboration in helping to reduce queries. Please note the key reminders below:

- ☺ **Day 10:** Please ensure collection of Serum CRP, faecal calprotectin, and MTWSI; avoid unblinded or out-of-window visits
- ☺ **Day 56:** Please ensure collection of CRP, faecal calprotectin, and MTWSI
- ☺ **Near miss (dispensing):** Two participants were randomised simultaneously, resulting in transposed participant IDs and incorrect kit numbers on prescriptions. Please ensure prescriptions are processed separately
- ☺ **Consent forms:** Questions Q10, Q13, and Q14 must be initialled, not circled
- ☺ **Screening logs:** Only REDACTED screening logs should be sent to HHTU
- ☺ **Pregnancy testing:** Required at Screening, Week 4 & 8 for all WOCBP
- ☺ All pregnancies must be reported, regardless of treatment

TIPS AND BEST PRACTICE

Emergency Unblinding

With a recent emergency unblinding error we would like to remind all teams of the correct procedure and thank you for your ongoing compliance.

Patients who are not responding to treatment by Day 3 should not be unblinded on Sealed Envelope to select rescue therapies.

Please follow the correct workflow:

- **Complete the Day 3 CRF**
- **Complete the Clinical Response CRF**
- **RCC will then guide you through the appropriate sub-studies**

Please contact HHTU and chief investigator on phone **07787227885** or **07453240514** in all circumstances considering unblinding for rescue therapy for non-response.

Moving to a sub study video link

YouTube: https://youtu.be/iFS5gXi_2fw

HHTU Box: <https://hhtu.box.com/s/5i1n9jv3pqj7rms6xwi9zs4g4e26c2v9>

ASSOCIATE PI SCHEME

Supporting ACESO Recruitment!

- ☺ The ACESO study is registered with the NIHR Associate PI Scheme, and several sites have successfully used the Associate PI Scheme to support study delivery and boost recruitment.
- ☺ The Associate PI Scheme offers a 6-month, in-work training opportunity, providing additional site support while developing future research leaders.
- ☺ Sites with an Associate PI have shown improved capacity and engagement.
- ☺ We encourage other sites to consider joining the scheme and benefit from the positive experiences seen across ACESO.

Please contact the CI if you are interested in registering.

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ACESO Trial SITE LEADERBOARD



Site	PI Name	Site Opening	Total recruitment	Recruitment in last 2 months
ACE-01 Hull	Prof. Shaji Sebastian	April	41	6
ACE-02 Cambridge	Dr Tim Raine	May	16	2
ACE-03 St Georges	Dr Sailish Honap	May	16	4
ACE-18 Wolverhampton	Dr Philip Harvey	September	15	1
ACE-23 Imperial	Dr James Alexander	November	9	2
ACE-05 Barts	Dr Gareth Parkes	July	9	1
ACE-04 Glasgow: GRI	Prof. Daniel Gaya	June	9	0
ACE-28 Maidstone	Dr Paul Blaker	October	8	1
ACE-10 Devon	Dr Jonathan Digby-Bell	May	7	1
ACE-07 Guys	Dr Shuvra Ray	October	6	2
ACE-11 Oxford	Dr Alissa Walsh	August	6	1
ACE-14 Leeds	Dr Christian Selinger	October	6	0
ACE-16 Newcastle	Dr Andrew King	September	5	1
ACE-27 Bristol	Dr Susanna Meade	October	5	1
ACE-06 Lothian	Dr Shahida Din	July	5	0
ACE-09 Kings	Dr Alexandra Kent	August	5	0
ACE-12 Shrewsbury	Dr Jeffery Butterworth	November	4	3
ACE-13 Glasgow QEUH	Dr John Paul Seenan	July	4	0
ACE-21 St Marks	Dr Ravi Misra	October	4	0
ACE-22 Somerset	Dr Emma Wesley	September	4	0
ACE-20 Chelsea	Dr Alice Moore	October	4	0
ACE-15 Manchester	Prof. Jimmy Limdi	August	4	0
ACE-29 Homerton	Dr Nishani Jayasooriya	November	3	2
ACE-08 Kettering	Dr Ajay Verma	May	3	1
ACE-25 Cardiff	Dr Dharmaraj Durai	December	2	1
ACE-26 Belfast (Ulster)	Dr Patrick Allen	November	2	0
ACE-24 Southampton	Prof. Fraser Cummings	November	1	1
ACE-30 Antrim	Dr Kok Diong	December	0	0