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Does NIGHT-time dialysis improve quality of LIFE?

Submission date
03/07/2020

Recruitment status
No longer recruiting

Registration date
14/07/2020

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Kidney dialysis is a lifesaving treatment for patients with kidney failure with around 24,000 patients receiving regular haemodialysis at a hospital or in a satellite clinic in the UK. Despite the benefits of receiving treatment, people with kidney failure who are on dialysis suffer from lots of intrusive symptoms and ultimately their lives are shortened because of this devastating disease. Most patients have a set dialysis appointment time lasting for 4 hours, 3 times per week, with travel time in addition. This is mainly because it is convenient for the hospital and not the patient. Studies have shown that being treated with the dialysis machine for longer has benefits, but the hard fact is that medical teams struggle to schedule more flexible or extended dialysis schedules due to the volume of patients and finite numbers of machines and staff.

In-centre nocturnal haemodialysis offers patients something different; the opportunity to have their treatment overnight in a hospital or satellite dialysis clinic while they sleep. Studies suggest that people who have their dialysis overnight may live longer, feel better and may be able to live a life which is closer to normal. Because overnight dialysis (typically 6-8 hours) is a lengthier treatment, it rids the blood of more waste and excess water, acting more like a patient's normal kidneys which would be working 24/7. As it removes fluid more slowly, it also helps heart function. Importantly, it frees the person up during the day to socialise, work and care for others.

What we know about doing dialysis for longer isn't perfect though. People who choose to do more dialysis may feel better and live longer for other, completely unrelated reasons. The only way to know for sure is to compare longer treatment times overnight with the standard 4-hour daytime treatment in a well-designed clinical trial. Previous trials haven't always measured what matters to people with kidney failure which has made it difficult to assess the impact of a particular treatment on real lives. To make sure these mistakes are not repeated, the current study has been designed with the help of dialysis patients and medical teams from centres that are already offering overnight dialysis and also from those that don't.

This study asks the question whether six-months of overnight dialysis, performed three times a week in a hospital or satellite centre, improves the quality of life of patients with kidney failure, as compared to those who have shorter dialysis sessions during the day. People who are suitable

and consent to take part (and who require dialysis for kidney failure) will be allocated at random to either nocturnal dialysis or daytime dialysis, which means their treatment will be determined by chance. This is done to create two groups of patients that are as similar as possible, allowing us to compare the two treatments fairly. Quality of life will be measured after 6-months of treatment using questionnaires that have been specifically designed for kidney patients. We will also collect information on the extra costs of night-time dialysis, to see whether the new treatment is more cost-effective than conventional dialysis care, for the person and the health service. Finally, we will evaluate the experiences of patients who are enrolled in the study to identify barriers to how the treatment would be rolled out across the NHS, if we were to find that it does benefit patients.

Who can participate?
Adult patients who have been receiving haemodialysis for over 3 months

What does the study involve?
Participants will be randomly allocated to receive either: night-time haemodialysis (with sessions lasting between 6 and 8 hours, in-centre, 3 times per week), or standard care (daytime dialysis, with sessions lasting between 3.5 and 5 hours, in-centre, 3 times per week), for 6 months.

What are the possible benefits and risks of participating?
There are no guaranteed benefits to taking part in the study. Night-time in-centre haemodialysis offers patients the opportunity to have their treatment overnight in a hospital or satellite dialysis clinic while they sleep. It is thought that night-time dialysis will free up patients' time during the day to socialise, work and care for others. All participants taking part in this study will also be helping to make a significant contribution to research into both daytime and night-time dialysis, which may improve future treatment. It is hoped that the results of the study will help us design improved treatments for other kidney patients in the future.

Participants randomised to night-time dialysis will be sleeping in a clinic rather than their own bed while undergoing treatment. It may, therefore, take them a while to get used to sleeping through treatment and in an unfamiliar environment. To help counteract this, participants will be provided with a ‘starter pack’ which will include a blindfold and ear plugs to help them sleep. The use of ‘soft close’ bins will be recommended at the dialysis unit to help minimise disruption.

If participants are randomised to night-time dialysis, their dialysis prescription may change. Dialysis prescriptions and dietary advice are individualised and each participant's supervising consultant will review their prescription on a monthly basis, just as they do with all patients on dialysis, and make changes as appropriate. This will not change and participants will continue to be reviewed on a monthly basis just as if they were receiving daytime dialysis. The research team will also be available to offer any guidance they may need to help with this. There may be less opportunity to access additional resources face-to-face, e.g. doctors and dietitians, during a night shift. However, this will be replaced with phone calls to ensure participants receive the care they need.

It is also possible that more dialysis may cause a faster decline in patients’ own remaining kidney function, although this is not known for sure, nor is it known what the consequences of this might be. This forms part of the study and the results will help to confirm if certain patients would be better suited to nocturnal dialysis than others.

Serious adverse events (SAEs)
Common non-life-threatening symptoms such as constipation, diarrhoea, headache, etc. do not need to be reported for this study.

It is expected that participants will experience a significant number of underlying health conditions and consequently an increased number of expected hospital admissions. Therefore only SAEs that are clearly related to the study intervention and of a serious nature will subject to expedited reporting to the Sponsor. This will comprise:
1. Issues around vascular access, i.e. needle dislodgement during dialysis, causing bleeding
2. Events that occur as a direct result of changes to a participant's dialysis prescription, e.g. hypokalaemia or hypophosphataemia
3. Anything else in the Investigator's opinion that is related and unexpected.

All other SAEs will be recorded using the SAE Log CRF, which will document SAE name /description, outcome, treatment, severity, expectedness and relatedness to the study intervention. SAE data will be recorded on the Macro database at regular intervals so that LCTU can generate up-to-date reports for the annual DSMC meetings. The DSMC will review the listings for clinical relevance and advise the TSC and Sponsor on the suitability of the continuance of the study following their review of the ongoing safety data and whether any further data should be collected or additional analyses undertaken.

Where is the study run from?
18 haemodialysis units across England, Scotland, Wales and Northern Ireland (UK)

When is the study starting and how long is it expected to run for?
From January 2020 to April 2025

Who is funding the study?
National Institute for Health and Care Research Health (NIHR) Technology Assessment (HTA) Programme (UK) (ref: NIHR127440)

Who is the main contact?
Central coordinating centre: nightlife@leicester.ac.uk
Prof James Burton (CI): jb343@leicester.ac.uk
Dr Katherine Hull (Clinical Research Fellow): kh326@leicester.ac.uk

Contact information

Type(s)
Public

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Type(s)
Scientific

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ORCID ID
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+44 (0)116 258 8043
jb343@le.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280452

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 280452, UOL0744

Study information

Scientific Title
A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus daytime haemodialysis using a mixed methods approach

Acronym
NightLife

Study objectives

The overall aim of this study is to test the clinical and cost effectiveness of thrice weekly, extended hours nocturnal dialysis compared to standard dialysis care thrice weekly during the day.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 11/12/2020, West Midlands - Edgbaston Research Ethics Committee (The Royal College of Surgeons of Edinburgh, 85-89 Colmore Row, Birmingham, B3 2BB, UK; +44 (0)20 7104 8112; edgbaston.rec@hra.nhs.uk), ref: 20/WM/0275
2. CAG support 11/12/2020, Confidentiality Advice Team - Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, UK; +44207 104 8100; cag@hra.nhs.uk), CAG ref: 20/CAG/0136

Study design
Pragmatic two-arm multi-centre randomized controlled trial with a health economic analysis. An internal pilot, an ongoing process evaluation and a Quintet recruitment intervention are embedded in this study.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Haemodialysis, renal failure

Interventions
Current intervention as of 14/05/2021:

Participants will be randomised to either:
1. Intervention arm where participants will receive 6 - 8 h of in-centre haemodialysis delivered overnight, 3 times per week for 6 months.
2. Standard care arm where participants will receive 3.5 - 5 h of in-centre haemodialysis, 3 times per week during the day for 6 months.

Randomisation: Participants will be randomised to an intervention group immediately after consent is taken using a ratio of 3 allocations to daytime haemodialysis to 4 allocations to extended hours nocturnal dialysis (1.33:1 ratio). Randomisation will be performed via a web-based system (Sealed Envelope). The unequal allocation in favour of the intervention will account for the anticipated 25% non-adherence rate in the intervention group (patients who start nocturnal dialysis but revert to daytime dialysis within the first 2 weeks.

Internal pilot: During the first 12 months of the recruitment period the feasibility of completing the study in the desired time frame will be assessed using an internal pilot. Based on investigator experience, the following targets will be set:
1. Recruit a minimum of 2 new units per quarter; 8 units initiated at 12 months
2. Randomise an average of 12 patients per unit in the first quarter (i.e. 6 patients will start in-centre nocturnal dialysis); 96 participants randomised at 12 months

3. Experience a maximum 25% drop out rate in the first 2 weeks of starting in patients randomised to in-centre nocturnal dialysis; participant drop out in first 2 weeks of nocturnal dialysis is <25% at 12 months
4. Encounter a dropout rate of no more than 15% across the two study arms as a result of death, kidney transplantation and other factors (e.g. moving out of area); remaining loss to follow-up is <15% at 12 months

Embedded process evaluation: A process evaluation will provide formative evaluation of the study processes and activities, in order to refine and amend where needed, and an evaluation of the intervention's implementation, including: assessment of whether and how well implementation is per protocol (components, timing and duration etc.) and identification of the contextual factors that influence its implementation and adoption. This will involve a researcher conducting observations in the dialysis units over the course of the NightLife study and conducting semi-structured interviews with staff, patients and/or visitors. In the lead up to the study (before observations begin) a researcher will visit each dialysis unit and explain to staff and patients what will be involved in the process evaluation (observations, document collation and interviews); this will give staff and patients the chance to ask questions about the study and express any concerns. It is anticipated that observations will be made in, and collating documentation obtained from, approximately half the total number of sites (n=9); with typically, 2-3 visits per site at different time-points (e.g. pre-intervention, during the training period and during INHD delivery).

An alternative method of qualitative data collection has been introduced to add resilience to the study in the COVID-19 era, thus making the deliverability of the process evaluation more robust. This will involve semi-structured interviews with staff and virtual photovoice with patients. This will assist the researcher to gain an understanding of usual haemodialysis practice and the patient experience of this where observational research cannot take place due to COVID-19 restrictions, but will also continue to be a flexible option for staff members and patients going forward. An electronic consent process has also been introduced to add resilience where face-to-face consent is not
feasible.

QuinteT Recruitment Intervention (QRI): Two key recruitment concerns were raised through the PPIE/staff discussions in the lead up to the grant application: (i) the potential for 'resentful demoralisation' in patients allocated to the control group, and (ii) the possibility that clinicians would consciously or sub-consciously discuss the study with select patients, rather than the full spectrum of eligible patients. An integrated QRI to optimise recruitment processes is planned to mitigate and address these issues. This will seek to understand the factors influencing recruitment and retention in 'real time', and then use these insights to inform interventions designed to improve recruitment processes for the remainder of the study. The overall aim of this work is to ensure all eligible patients receive full, clear, and accurate information about the study, to enable an informed decision about participation. This will be achieved by identifying, understanding, and addressing equipoise issues amongst clinicians, and gaining a better understanding of how the study is communicated to/understood by patients. Helping patients to understand the potential advantages/disadvantages of both study arms is planned with the aim of reducing the risk of resentful demoralisation and crossovers. The QRI employs qualitative and mixed-method approaches to understand recruitment issues rapidly, including semi-structured interviews and analysis of audio-recorded recruitment discussions (Phase 1), and then uses this evidence to design and implement tailored strategies to optimise recruitment processes (Phase 2). This work package will complement and build upon the component of the internal pilot and process evaluation which involves monitoring recruitment and retention. Audio-recordings of recruiter-patient discussions do not require the presence of a researcher.

The original protocol processes can be followed if recruitment consultations continue in person. If recruitment consultations need to be conducted remotely via telephone due to COVID-19 restrictions, equipment will be provided to allow the recruiters to audio-record their telephone calls with patients (upon receipt of appropriate consent).

Health economics evaluation: The difference in resource use, costs, and quality of life adjusted life years (QALYs) between the intervention and control arms will be calculated. An intention to treat and per-protocol analysis will be performed (the latter informing the beyond study model below). This will reflect set-up and per session costs, ultimately reporting the cost per QALY gained; that is, the ratio of the change in costs to the change in QALYs between the 2 groups. The incremental cost per dialysis treatment and cost per patient per year will also be calculated. A sensitivity analysis will be undertaken to assess the robustness of the results to any assumptions made in the analysis. Resource use, expenditure data, and broader social data will be collected from participant self-completed questionnaires at 1-, 3- and 6-months as well as routine clinical databases (HES, ONS and UKRR). A diary will also be provided to participants to record their healthcare usage and subsequently use this information to aid the completion of the aforementioned self-completed questionnaire. The EQ-5D-5L questionnaire will be used to determine health state descriptions for the five components combined with preference-weighted health-related quality of life index scores (as approved by NICE) to generate QALY profiles for the cost-effectiveness analysis. A staff questionnaire to inform the health economic evaluation will also be completed by a senior nurse responsible for the haemodialysis unit before and after implementation of the intervention. This will help us to understand how staffing and equipment differ between usual care and in-centre nocturnal dialysis.

NightLife Cardiac MRI (CMR) sub-study: A separately funded CMR sub-study (British Heart Foundation, ref PG/20/10132) will take place in a selection of the 18 sites participating in the main NightLife RCT. Please refer to record https://www.isrctn.com/ISRCTN11722317 for further information.

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Previous interventions:

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record their healthcare usage and subsequently use this information to aid the completion of the aforementioned self-completed questionnaire. The EQ-5D-5L questionnaire will be used to determine health state descriptions for the five components combined with preference-weighted health-related quality of life index scores (as approved by NICE) to generate QALY profiles for the cost-effectiveness analysis. A staff questionnaire to inform the health economic evaluation will also be completed by a senior nurse responsible for the haemodialysis unit before and after implementation of the intervention. This will help us to understand how staffing and equipment differ between usual care and in-centre nocturnal dialysis.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 17/02/2023:

Kidney Disease Quality of Life (KDQoL) total score (calculated from the KDQoL-SF questionnaire) measured over 6 months

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Previous primary outcome measure:

Quality of life measured using the composite score from the Kidney Disease Quality of Life tool (KDQoL) at 6 months

Key secondary outcome(s))
Current secondary outcome measures as of 17/02/2023:

1. Kidney Disease Quality of Life (KDQoL) total score (calculated from the KDQoL-SF questionnaire) measured at 1-, 3- and 6-months
2. Kidney Disease Quality of Life (KDQoL) domains (calculated from the KDQoL-SF questionnaire) measured over 6-months
2.1. Physical component summary score
2.2. Mental component summary score
2.3. Kidney summary score
2.4. Kidney disease component summary score
3. Additional Patient Reported Outcome Measures assessed at baseline, 1, 3 and 6 months:
3.1. Health-related quality of life measured using the EQ-5D-5L
3.2. Levels of fatigue measured using the SONG Haemodialysis Fatigue measure
3.3. Sleep quality measured using the Pittsburgh Sleep Quality Index
3.4. Time to recovery after dialysis measured using a simple question on Time to Recovery (TTR) in minutes after dialysis
3.5. Cognitive health assessed using the Montreal Cognitive Assessment at baseline, 3 months and 6 months
4. Safety measures:
4.1. Residual kidney function measured using urine collection with paired blood samples taken at the time of dialysis to give standard measures of urine volume, urea and creatinine clearance at baseline and 6 months, and serum beta-2 microglobulin in blood samples taken monthly between baseline and 6 months
4.2 Serious adverse events (SAEs)
4.2.1. SAEs in totality (rate/years)

4.2.2. Vascular access complications that lead to SAEs (rate/years)
4.2.3. Dialysis prescription changes that lead to SAEs (rate/years)
4.3. Clinical outcomes (cardiovascular events, CVD death, mortality) (rate/years) collected using Hospital Episode Statistics (HES) and Office of National Statistics (ONS) databases (or regional equivalent) on the three year anniversary of the last participant last visit
5. Measures of process:
5.1. Adherence to the intervention
5.1.1. Hours per session
5.1.2. Number of sessions missed
5.1.3. Number of sessions not meeting time criteria
5.1.4. Temporary change from treatment allocation
5.2 Clinical results and dialysis parameters
6. Cost-effectiveness analysis measures:
6.1. Resource use and expenditure measured using both: a self-completed health economics questionnaire at baseline and a resource use/expenditure questionnaire and diary at 1, 3, and 6 months from participants; and a staff questionnaire completed by a senior nurse responsible for the haemodialysis unit before and after implementation of the intervention
6.2. Cost per QALY gained

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Previous secondary outcome measures as of 14/05/2021:

1. Quality of life measured using the Kidney Disease Quality of Life tool (KDQoL) at 1 and 3 months
2. Additional Patient Reported Outcome Measures assessed at baseline, 1, 3 and 6 months:
2.1. Health-related quality of life measured using the EQ-5D-5L
2.2. Levels of fatigue measured using the SONG Haemodialysis Fatigue measure
2.3. Sleep quality measured using the Pittsburgh Sleep Quality Index
2.4. Time to recovery after dialysis measured using a simple question on Time to Recovery (TTR) in minutes after dialysis
2.5. Cognitive health assessed using the Montreal Cognitive Assessment at baseline, 3 months and 6 months
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3.1. Residual kidney function measured using urine collection with paired blood samples taken at the time of dialysis to give standard measures of urine volume, urea and creatinine clearance at baseline and 6 months, and serum beta-2 microglobulin in blood samples taken monthly between baseline and 6 months
3.2. Vascular access complications that lead to AEs or hospital admission using site records between baseline and 6 months
3.3. Adverse events using site records of the number and type of adverse events (including mortality, cardiovascular events, hospitalisation and vascular access interventions) collected using Hospital Episode Statistics (HES) and Office of National Statistics (ONS) databases (or regional equivalent) at 3 years follow up
3.4. Clinical outcomes (cardiovascular events, CVD death, mortality) collected using Hospital Episode Statistics (HES) and Office of National Statistics (ONS) databases (or regional equivalent) at 3 years follow up
4. Process evaluation measures:
4.1. Adherence to the intervention and hours on dialysis at 6 months
4.2. Impact of longer dialysis on the clinical results/dialysis parameters using routinely collected data from dialysis units for required data return to the UK Renal Registry (UKRR) and Scottish Renal Registry (SRR), extracted at 1, 2 and 3 years

5. Cost-effectiveness analysis measures:
5.1. Resource use and expenditure measured using both: a self-completed health economics questionnaire at baseline and a resource use/expenditure questionnaire and diary at 1, 3, and 6 months from participants; and a staff questionnaire completed by a senior nurse responsible for the haemodialysis unit before and after implementation of the intervention
5.2. Cost per QALY gained

Previous secondary outcome measures:

1. Quality of life measured using the Kidney Disease Quality of Life tool (KDQoL) at 1 and 3 months
2. Additional Patient Reported Outcome Measures assessed at baseline, 1, 3 and 6 months:
2.1. Health-related quality of life measured using the EQ-5D-5L
2.2. Levels of fatigue measured using the SONG Haemodialysis Fatigue measure
2.3. Sleep quality measured using the Pittsburgh Sleep Quality Index
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5. Cost-effectiveness analysis measures:
5.1. Resource use and expenditure measured using both: a self-completed health economics questionnaire at baseline and a resource use/expenditure questionnaire and diary at 1, 3, and 6 months from participants; and a staff questionnaire completed by a senior nurse responsible for the haemodialysis unit before and after implementation of the intervention
5.2. Cost per QALY gained

Completion date
30/04/2025

Eligibility

Key inclusion criteria

1. Patients established on haemodialysis for ≥3 months (i.e. prevalent dialysis patients)
2. Aged ≥18 years
3. Able to give informed consent
4. Able to participate fully in the interventions and follow-up procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
100

Key exclusion criteria
Current exclusion criteria as of 14/05/2021:
1. Currently on in-centre nocturnal dialysis, or less than 3 months since stopping
2. Less than 3 months since stopping daily extended daytime or nocturnal dialysis
3. Patients for whom extended dialysis is clinically indicated (e.g. calciphylaxis, pregnancy)
4. Scheduled for living donor kidney transplant
5. Plans to change dialysis modality or centre in the next 6 months
6. Life expectancy of <6 months
7. Current participation in an interventional trial with conflicting therapies or primary outcomes

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1. Currently on in-centre nocturnal dialysis, or less than 3 months since stopping
2. Less than 3 months since stopping daily extended daytime or nocturnal dialysis
3. Patients for whom extended dialysis is clinically indicated randomisation to standard hours care of 4 h thrice weekly during the day would be clinically unacceptable (e.g. calciphylaxis, pregnancy)
4. Scheduled for living donor kidney transplant
5. Plans to change dialysis modality or centre in the next 6 months
6. Life expectancy of <6 months
7. Current participation in an interventional trial with conflicting therapies or primary outcomes

Date of first enrolment
01/10/2021

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University Hospitals of Leicester NHS Trust
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Southern Health and Social Care Trust
Southern Area College of Nursing
Craigavon Area Hospital
68 Lurgan Road, Portadown
Craigavon
United Kingdom
BT63 5QQ

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/08/2023	14/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes