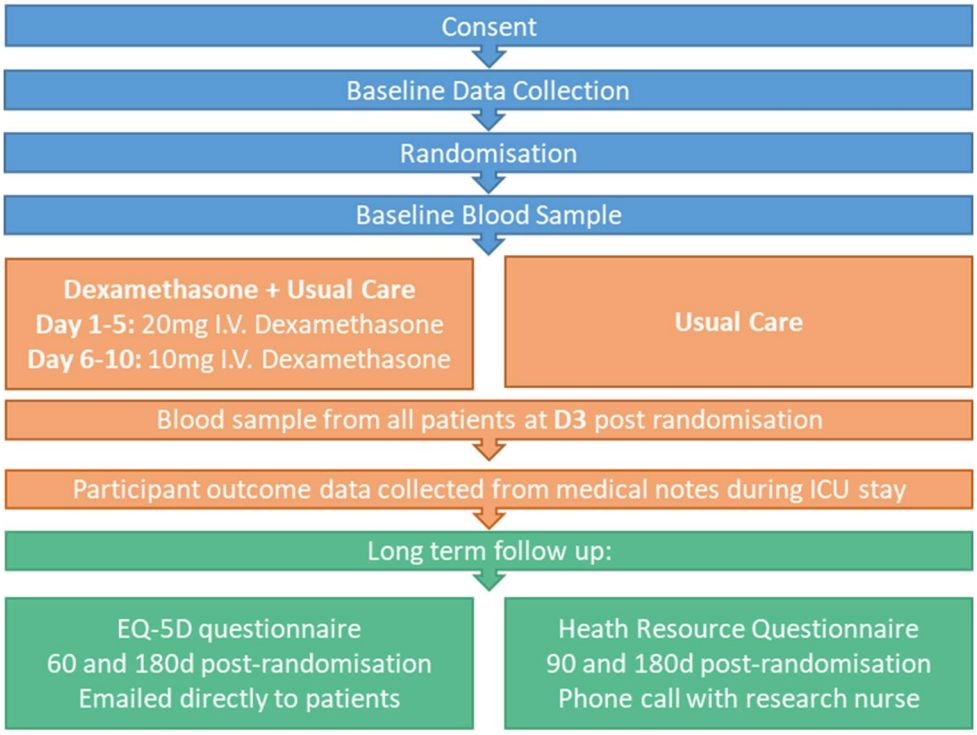
***Glu*cocorticoids in adults with *A*cute *R*espiratory *D*istress *S*yndrome (GuARDS Trial)**

Trial Title	***Glu*cocorticoids in adults with *A*cute *R*espiratory *D*istress *S*yndrome: A randomised, parallel-group, allocation-concealed, open label, pragmatic, group sequential design, clinical and cost- effectiveness trial with internal pilot**
Study Acronym	GuARDS Trial
Clinical Phase	Phase IV
Trial Design	Randomised, parallel-group, allocation-concealed, open label, pragmatic, group sequential design
Trial Participants	1708
Planned Number of Participants	1708
Planned Number of Sites	At least 60
Countries Anticipated to be Involved in Trial	All 4 UK Home Nations (England, Wales, Northern Ireland, and Scotland)
Treatment Duration	10 days
Follow up Duration	180 days
Total Planned Trial Duration	60 months
Primary Objective	To determine the clinical effectiveness of dexamethasone on the primary outcome of 60-day mortality,
Secondary Objectives	To determine the clinical effectiveness of dexamethasone in moderate to severe ARDS To assess the cost-efficiency of dexamethasone plus usual care versus usual care alone in the treatment of ARDS, as per NICE reference case specifications modelled over 1, 3, and 5 year, and lifetime time horizons.
Primary Endpoint	All-cause mortality at 60-days from randomisation
Secondary Endpoint	**In hospital** Extubation; Re-intubation; Duration of stay in intensive care unit from randomisation; duration of stay in hospital from randomisation **At 60 days** Health-related quality of life; **At 90 days** All-cause mortality; Health Service Use Follow-up **At 180 days** Health-related quality of life; All-cause mortality; Health Service Use Follow-up
IMP(s)	Dexamethasone
IMP Route of Administration	Intravenous

Aim(s) of the trial

The aims of our study is to find out if dexamethasone treatment in patients with ARDS can save lives, reduce the need for extended ICU care, improve longer term patient quality of life and find the best value for the public and health services.

Trial Overview



Consent

We expect the majority of patients to lack capacity to consent at the time of screening and enrolment to the trial.

Efforts should be made to get consent from a Personal Legal Representative (PerLR) where possible. If there is not one present in the ICU after 48h efforts can be made to contact the PerLR by phone. If the PerLR is unavailable after 3 attempts a Professional Legal Representative can be approached for consent.

Once patients have regained capacity they will be asked to consent to continue in the trial.

Data Collection

Baseline data and blood samples are collected after randomisation but prior to any treatment and will be collected in the trial eCRF. Much of the baseline data is collected routinely as part of normal clinical care.

Data for the secondary outcomes are collected to align with the CoVENT core outcome set for ventilation trials.

There will be an additional research blood sample at 3 days post randomisation.

There will be a status check and follow-up Heath Resource Questionnaire at 90 and 180d post randomisation.

Site Payments

	Area of Cost	Payment
1.	Band 6 Research Nurse for recruitment (10h per patient)	£277.50 (per participant)
2.	Pharmacy fee (set up and close down)	£867
3.	Pharmacy IMP management fee	£294 (per year)