

## SENTINEL

A Randomised controlled trial to investigate the effect of a simultaneous sentinel skin flap transplant on lung transplantation

Funding: NIHR

Sponsor: University of Oxford

Approvals to date: RINTAG (NHSBT)

Centres : Birmingham, Harefield, Manchester, Newcastle, Papworth

Recruitment: 152.

Inclusion:

1. Intended recipient of a lung transplant
2. Aged 18 years or over
3. Participants capable of giving informed consent

Exclusion:

1. Any significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to comply with trial procedures
2. Severe peripheral vascular disease with no vessels available for inset of the skin flap.
3. Donor consent not given, or donor not suitable ( paediatric, ischaemic limbs, occluded peripheral vessels) at time of transplantation

Randomisation: 1:1. 76 in each arm lung alone vs lung and sentinel skin flap

Randomisation will only be performed once an offer of lung *and* skin have been made.

Start date: March 2023

Consent: two stage , one on waiting list and confirmation before transplantation.

Recruitment period 3 years.

Study follow up period for each participant : 12 months

Primary Outcome: lung rejection events

Secondary outcomes: skin rejection events/ immunosuppression/survival -organ and patient/ Lung function/ safety events ( GVHD/DnDSA/ chronic rejection/ etc ) /HRQoL/ mechanistic studies

Investigators:	Plastic sentinel skin flap Surgeons:
• Professor Patrick Bossuyt	• <i>Henk Giele</i>
• Ms Becky Clarke	• <i>Kai Wong</i>
• Dr Elizabeth Conroy	• <i>George Filobbos</i>
• Mr John Dunning	• <i>Baljit Dheansa</i>
• Professor Andrew Fisher	• <i>Jason Wong</i>
• Professor Peter Friend	• <i>Sarah Tucker</i>
• Dr Joanna Hester	• <i>Daniel Saleh</i>
• Prof Fadi Issa	• <i>Juan Berner</i>
• Mr Simon Knight	• <i>James Bedford</i>
• Dr Jasvir Parmar	• <i>Adam Reid</i>
• Dr Anna Reed	• <i>Mark Foster</i>
• Dr Fernando Riesgo Gil	• <i>James Baden</i>
• Karthik Santhankrishnan	•
• Dr Richard Thompson	•
• Mr Robert Burns	•