



National Trials Recruitment Update

11th October 2024

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National Trials

- **Recruitment Open**



- **Recruitment closed – In follow up**

- **Results pending**



- **Results presented**



- **New Trials -**

UK-MAT

DRAGON

a trial by the
NIHR Global Health Research Unit on
Global Surgery

Recruitment open



DOMINO-DFU – Diagnosis of Osteomyelitis: investigation optimisation in diabetic foot ulcers

CI A/Professor David Russell, Leeds Institute of Clinical Trial Research

Multi-centre, prospective, clinical cohort of patients with Diabetic Foot Ulcers

Phases

- 1 - Describe current ‘standard care diagnostic pathway’ and treatment of DFO
- 2 - Identify the optimal bone biopsy method - ‘remote’ or ‘through-the-ulcer’
- 3 - Develop and validate a diagnostic prediction model for DFO infection to improve diagnostic and therapeutic yield compared to current clinical standard.

Recruitment period due to end = **August 2025**

Recruitment target = **Overall cohort: 4550**

Actual recruitment = **996**

- Phase 1 high risk: **225 (met target 225)**
- Phase 2 = **105 (target 192 Commenced Feb 2023)**
- Phase 3 target = **450 (Aiming for Autumn 2025 - funding)**





DOMINO-DFU



Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	Not participating
Worcestershire Acute Hospitals NHS Trust	Not participating
University Hospitals Birmingham NHS Foundation Trust	Not participating
Sandwell and West Birmingham Hospitals NHS Trust	12 (phase 1)
University Hospitals Coventry and Warwickshire NHS Trust	Not participating
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	Not participating

Reduction Of Surgical Site Infections using several Novel Interventions

CI Professor Thomas Pinkney, Birmingham Clinical Trials Unit

MAMS RCT to evaluate the use of three in-theatre interventions to reduce the incidence of SSI rates in patients undergoing surgery with an abdominal incision

- Three health technologies assessed versus their control arms (standard care):
- 1. **2% alcoholic chlorhexidine skin preparation – awaiting final analysis**
- 2. **Iodophor-impregnated incise drape (dropped after first interim analysis)**
- 3. **Gentamicin-impregnated collagen sponge (also dropped)**

ROSSINI-2 Extension Phase

4. Change of Gloves & Instruments immediately before abdominal wall closure
5. Dialkylcarbamoyl chloride (DACC) impregnated dressing

Recruitment due to end = **June 2026** Actual Recruitment = **129**

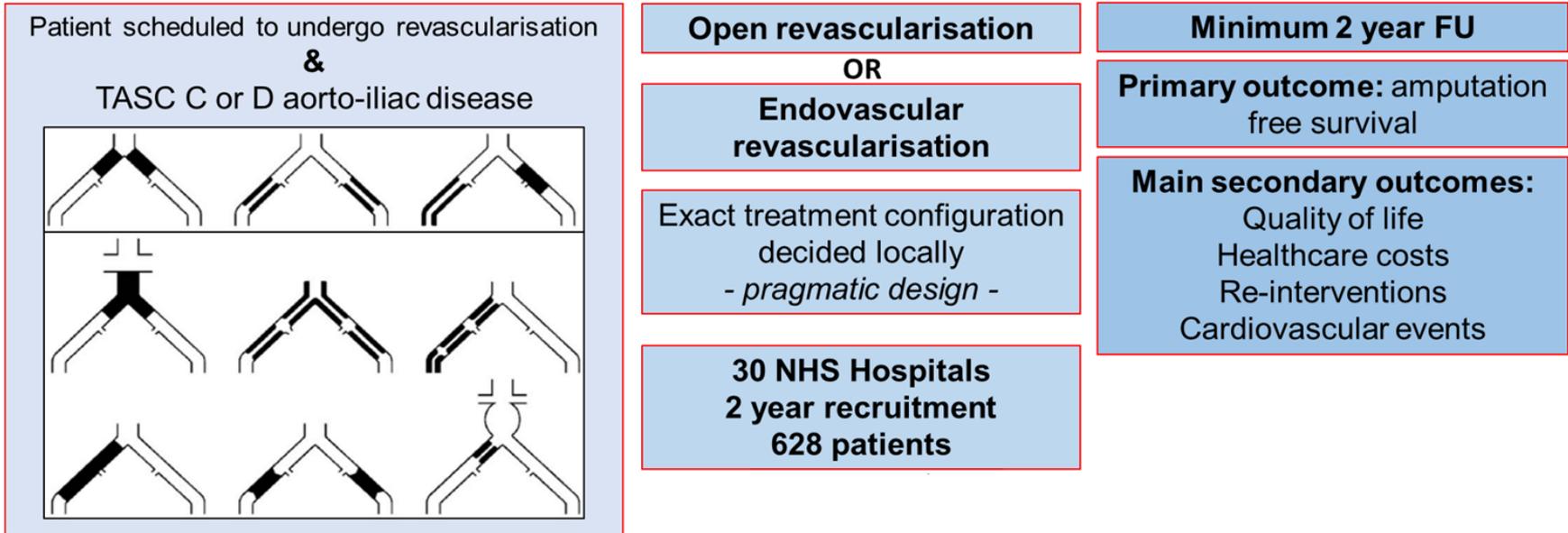
Recruitment target = **6610 (5152)- Additional 4269 over 26 months**

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	211 - March EXT 7
Worcestershire Acute Hospitals NHS Trust	147 Oct23 (not vascular pts)
University Hospitals Birmingham NHS Foundation Trust	1011 - March EXT 63 (Not vascular pts)
University Hospitals Coventry and Warwickshire NHS Trust	18 – March
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	65 - March

CI Professor Athanasios Saratzis, Leicester Clinical Trials Unit

A randomised controlled trial assessing the clinical and cost-effectiveness of Endovascular vs. Open revascularisation in severe oCclusive aorto-iliac disease.



Recruitment due to end: **October 2025**

Recruitment target: **628**

Current Recruitment: **103 (7/10/24)**



EVOCC



Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	7
Worcestershire Acute Hospitals NHS Trust	0
University Hospitals Birmingham NHS Foundation Trust	7
University Hospitals Coventry and Warwickshire NHS Trust	Due to open Oct
University Hospitals of North Midlands NHS Trust	0
The Shrewsbury and Telford Hospital NHS Trust	Not participating

DRESSING - DACC in the REduction of Surgical Site INfection

CI George Smith, Hull University Teaching Hospitals NHS Trust

Multicentre randomised controlled trial to assess the effectiveness of Dialkylcarbamoylechloride (DACC) coated postoperative dressings versus standard care in the prevention of Surgical Site Infection in clean or clean-contaminated, vascular surgery.

Population Adults ≥ 18 yrs undergoing clean or clean-contaminated lower limb vascular surgery, with wounds to be closed by primary intention.

Intervention DACC coated dressing

Control Non DACC coated dressing

Outcome The incidence of surgical site infection (SSI) – defined by CDC criteria or total ASEPSIS score $\geq 21(1)$ within 30 days of surgery

Recruitment target **718** **Follow up** 3 months (30 days for local site)

Actual recruitment **438 (61%) Recruitment due to end Sept 2025 – on target**

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	48-2nd highest recruiter
Worcestershire Acute Hospitals NHS Trust	Not participating
University Hospitals Birmingham NHS Foundation Trust	Not participating
University Hospitals Coventry and Warwickshire NHS Trust	0
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	Not participating

THRIVE- THRomboprophylaxis in Individuals undergoing superficial endoVenous treatment

CI Professor Alun Davies, Imperial College London

Multi-centre, assessor-blind, randomised controlled trial

Population - Adults undergoing endovenous interventions for varicose veins under local anaesthesia

Intervention/Comparator - Compressions stockings and –
- no LMWH
- single dose LMWH
- extended prophylaxis with DOAC
or LMWH (7, 10, 14 days)

Primary Outcome - Imaging confirmed lower limb DVT with or without symptoms, or PE with symptoms within 90 days of varicose vein treatment

Recruitment Target – 6660

Actual recruitment – 670 (7/10/24)

Internal pilot ended 30th Sept – 647/725



THRIVE

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	In Set Up
Worcestershire Acute Hospitals NHS Trust	16
University Hospitals Birmingham NHS Foundation Trust	Not participating
University Hospitals Coventry and Warwickshire NHS Trust	In Set Up
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	Not participating

PLACEMENT - Perineural local anaesthetic catheter after major lower limb amputation trial

CI – Mr D Bosanquet, Cardiff University

A phase III, pragmatic, open-label, two-arm, individually randomised controlled trial, comparing perineural catheter (PNC) and local anaesthetic infusion for the first five postoperative days after major lower limb amputation (MLLA) with no PNC.

Primary outcome Freedom from pain

Follow up Twice daily pain scores for the first 5 post-op days, then pain scores and QoL questionnaires at 3 and 6 months

Recruitment due to end = Mar 2025 – hoping to extend to Oct 2025

Recruitment Target = 650

Actual recruitment = 138 (30.9.24)

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	Not participating
Worcestershire Acute Hospitals NHS Trust	Not participating
University Hospitals Birmingham NHS Foundation Trust	Not participating
University Hospitals Coventry and Warwickshire NHS Trust	Not participating
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	Not participating

Results pending



MIDFUT – Multiple Interventions for Diabetic Foot Ulcer Treatment

CI A/Professor David Russell, Leeds Institute of Clinical Trial Research

Phase II/III, Multi arm multi stage (MAMS) RCT

Phase II:-

- TAU (Treatment as Usual)
- TAU + HD (Hydrosurgical debridement)
- TAU + HD + NPWT (Negative Pressure Wound Therapy)
- TAU + HD + DCD (Decellularised dermal allograft)
- TAU + HD + DCD + NPWT

Phase III:-

Investigate the clinical and cost effectiveness of a maximum of one treatment strategy continued from Phase II, compared to TAU alone

Recruitment closed = **31 Aug 2023 - Follow up ended 31 Aug 2024**

Recruitment target = **447 (245 phase II; 202 phase III)**

Actual recruitment = **213 (phase II)**

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	13
Worcestershire Acute Hospitals NHS Trust	Not participating
University Hospitals Birmingham NHS Foundation Trust	Not participating
University Hospitals Coventry and Warwickshire NHS Trust	11
University Hospitals of North Midlands NHS Trust	Not participating
The Shrewsbury and Telford Hospital NHS Trust	Not participating
Midlands Partnership NHS Foundation Trust	6

VenUS 6: A randomised controlled trial of compression therapies for the treatment of venous leg ulcers

CI Professor Jo Dumville, York Trials Unit

Three arms:-

- Evidence based compression (four-layer bandage, two-layer hosiery)
- Two-layer bandage
- Compression wrap

Recruitment closed = **Extended until Apr 2024**

Recruitment target = **675**

Actual recruitment = **637 (94.4%)**



Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	10
Worcestershire Acute Hospitals NHS Trust	Did not participate
University Hospitals Birmingham NHS Foundation Trust	12
University Hospitals Coventry and Warwickshire NHS Trust	Did not participate
University Hospitals of North Midlands NHS Trust	Did not participate
The Shrewsbury and Telford Hospital NHS Trust	3
Midland Partnership NHS Foundation Trust	8

SWHSI-2 Negative pressure wound therapy versus usual care for surgical wounds healing by secondary intention

CI Professor Ian Chetter, York Trials Unit

RCT to assess the clinical and cost effectiveness of NPWT in the management of SWHSI

Two arms:- NPWT
 Usual care (no NPWT)

Recruitment period = Closed 13th Jan 2023 –

12 month Follow up period completed

Recruitment target = 696

Actual recruitment = 686





SWHSI-2

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	43
Worcestershire Acute Hospitals NHS Trust	8
University Hospitals Birmingham NHS Foundation Trust	58
University Hospitals Coventry and Warwickshire NHS Trust	0
University Hospitals of North Midlands NHS Trust	0
The Shrewsbury and Telford Hospital NHS Trust	9

to establish the presence and severity of peripheral arterial disease in people with diabetes

CI Professor Alun Davies, Imperial College London

A multi centre, open trial to determine the diagnostic performance of index tests for the diagnosis of PAD in patients with diabetes as determined by a reference test (CTA or MRA)

- Audible handheld doppler
- Visual handheld doppler
- ABPI
- Exercise ABPI and TBPI

Follow up period ended = **14 Feb 2024**

Recruitment target = **730**

Actual Recruitment = **604**

Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	Did not participate
Worcestershire Acute Hospitals NHS Trust	6
University Hospitals Birmingham NHS Foundation Trust	Did not participate
University Hospitals Coventry and Warwickshire NHS Trust	Did not participate
University Hospitals of North Midlands NHS Trust	Did not participate
The Shrewsbury and Telford Hospital NHS Trust	Did not participate



Results presented

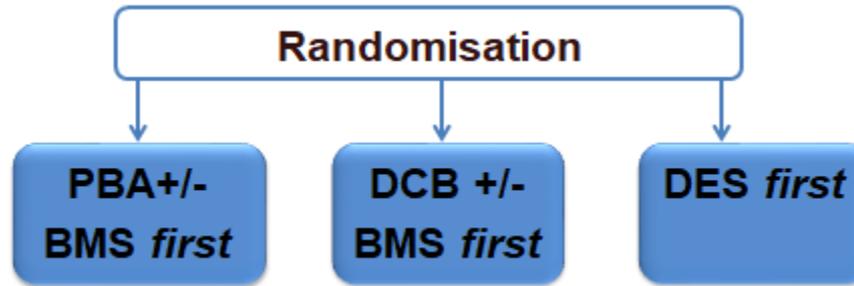




BASIL-3 – BALloon versus Stenting in severe Ischaemia of the Leg - 3

CI Professor Andrew W Bradbury, Birmingham Clinical Trials Unit

SLI due to FP, +/- IP, disease



Recruitment target = 477

Actual recruitment = 481

Recruitment closed = Aug 2021- 2 year follow up completed 31 Aug 2023

**Results presented at Charing Cross April 2024 –
No significant differences were found between the groups**



BASIL-3



Recruitment per site

SITE	NUMBER RECRUITED
The Dudley Group NHS Foundation Trust	22
Worcestershire Acute Hospitals NHS Trust	Did not participate
University Hospitals Birmingham NHS Foundation Trust	65
University Hospitals Coventry and Warwickshire NHS Trust	Did not participate
University Hospitals of North Midlands NHS Trust	Did not participate
The Shrewsbury and Telford Hospital NHS Trust	Did not participate

New trials

UK-MAT



UK-MAT

The UK Metformin Aneurysm study

CI –Professor Matt Bown

A multicentre, international, double-blinded, placebo-controlled, parallel-group, randomised controlled trial to determine the effect of metformin on abdominal aortic aneurysm (AAA) associated events, including AAA repair and AAA mortality (due to aneurysm rupture)

Population - Infrarenal AAA with a diameter between 35mm-49mm on imaging, no planned repair within the next 12 months

Intervention - Active treatment: metformin SR 3 x 500mg tablets once per day

Control - Matched placebo 3 x 500mg tablets once per day

Outcome - Primary outcome: AAA-related events defined as the occurrence of AAA repair or AAA mortality due to rupture

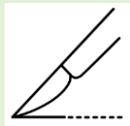
Study Duration = 5 years

Recruitment target = 1954 (**660** in UK)



Disposable versus reusable drapes and gowns for green operating theatres

Multicentre non-inferiority cluster randomised trial



Clean-contaminated, contaminated, or dirty surgery with an incision ≥ 5 cm



26,800 adults and children



134 hospitals (clusters)



INTERVENTION

Reusable drapes and gowns



COMPARATOR

Single-use drapes and gowns

Key outcomes: Clinical | Cost | Carbon

Process evaluation

Health economics

Carbon modelling

30 day follow up of routinely collected data

Join the DRAGON trial

- The DRAGON trial will run across the UK, Benin, Ghana, India, Mexico, Nigeria, Rwanda, South Africa.
- To get involved, complete a short survey at:
https://redcap.link/UK_DRAGON_Interest



In person registration
now OPEN!

<https://tinyurl.com/GreenSurg24>

Follow us on X
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information



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NIHR National Institute for Health and Care Research

UNIVERSITY OF BIRMINGHAM

GREENSURG

Research for Greener Surgery 2024

Tuesday 17th December 2024

The Great Hall at the University of Birmingham

Registration is now OPEN!

Scan the QR code or go to the link



<https://tinyurl.com/GreenSurg24>

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The poster features a collage of images: a cityscape with a prominent clock tower, solar panels in a field, and surgeons in an operating room.



Thank you

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