Prevention of microbial colonisation using ethylene diamine tetraacetic acid (EDTA) line locks and its effect on erythropoietin (EPO) resistance in haemodialysis patients using temporary vascular catheters - a prospective study

Submission date 12/09/2003	Recruitment status Stopped	 Prospectively registered Protocol
Registration date 12/09/2003	Overall study status Stopped	 Statistical analysis plan Results
Last Edited 17/08/2012	Condition category Surgery	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0436118126

Study information

Scientific Title

Study objectives

To determine whether bacterial colonisation and subsequent bacteremia can be reduced using EDTA salt line- locks.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Health condition(s) or problem(s) studied Haemodialysis

Interventions

Before-after trial; Laboratory study; Randomised controlled trial: 1. Standard vascular catheters for dialysis 2. Vascular catheter and EDTA line-lock

Intervention Type Procedure/Surgery **Phase** Not Specified

Primary outcome measure Eradication of bacterial colonisation.

Secondary outcome measures Not provided at time of registration

Overall study start date 01/04/2003

Completion date 03/04/2005

Eligibility

Key inclusion criteria Haemodialysis patients dialysing with a central venous catheter on EPO therapy.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Not provided at time of registration

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment 01/04/2003

Date of final enrolment 03/04/2005

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department of Renal Medicine Leeds United Kingdom LS1 3EX

Sponsor information

Organisation Department of Health (UK)

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.doh.gov.uk

Funder(s)

Funder type Hospital/treatment centre

Funder Name Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration