VITAL: VITamin E and Anaemia in dialysis patients in Leeds

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|------------------------------|--|--------------------------------|--|--|
| 23/04/2010 | | ☐ Protocol | | |
| Registration date 23/04/2010 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 20/07/2016 | Urological and Genital Diseases | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Simon Lines

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2009-017505-11

Protocol serial number

6879

Study information

Scientific Title

A study to assess the effects of a vitamin E bonded haemodialysis membrane on erythropoiesis simulating agent requirements and fibrin clot structure and function in chronic haemodialysis patients

Acronym

VITAL

Study objectives

Does dialysis with a vitamin E bonded haemodialysis membrane reduce erthyropoesis stimulating agent requirements over 12 months in chronic haemodialysis patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics Committee (REC) approved on the 26th February 2009 (ref: 08 /H1307/144)

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions

Control: Rexeed Dialyser

Intervention: Vitabran E dialyser

Follow Up Length: 12 month(s)

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vitamin E

Primary outcome(s)

Haemoglobin concentration and erythropoeisis stimulating agent requirements at 6 months and 12 months

Key secondary outcome(s))

Data collected at 6 and 12 months on:

- 1. Markers of oxidative stress
- 2. Fibrin clot structure

Completion date

01/02/2010

Eligibility

Key inclusion criteria

- 1. Dialysis patient managed by Leeds Teaching Hospitals NHS Trust Renal Unit
- 2. Established on HD for at least 3 months prior to entry into study
- 3. Patients expected to remain on haemodialysis for at least 6 months
- 4. Written consent and willingness to participate in the study
- 5. Aged greater than 18 years at point of entry into study
- 6. Patients on a 3 times a week dialysis schedule

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Unwillingness or inability to cooperate or give written informed consent
- 2. Terminally ill patients (expected survival less than 6 months)
- 3. Medical conditions requiring regular blood transfusion at the time of study enrolment
- 4. Any serious medical, social or psychological condition that in the opinion of the investigator would disqualify from participation
- 5. Patients with a significant inflammatory illness within 3 months as defined by a C-reactive protein (CRP) greater than 50 mg/L or 3 x patient's baseline CRP

Date of first enrolment

01/10/2009

Date of final enrolment

01/02/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Renal Medicine
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust (UK)

ROR

https://ror.org/00v4dac24

Funder(s)

Funder type

Industry

Funder Name

Asahi Kasei Medical Corporation (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|-------------------------|----------------|-----------------|
| Results article | results | 01/03/2014 | Yes | No |

Participant information sheet 11/11/2025 No Yes