

VITAL: VITamin E and Anaemia in dialysis patients in Leeds

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simon Lines

Contact details
Department of Renal Medicine
Beckett Street
Leeds
United Kingdom
LS9 7TF

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 stimulating 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 erythropoiesis 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 erythropoiesis 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

All

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