

# VITAL: VITamin E and Anaemia in dialysis patients in Leeds

<b>Submission date</b> 23/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/07/2016	<b>Condition category</b> 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**  
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## Additional identifiers

**EudraCT/CTIS number**  
2009-017505-11

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

Data collected at 6 and 12 months on:

1. Markers of oxidative stress
2. Fibrin clot structure

**Overall study start date**

01/10/2009

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 348

**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**

England

United Kingdom

**Study participating centre**

Department of Renal Medicine

Leeds

United Kingdom

LS9 7TF

## Sponsor information

**Organisation**

Leeds Teaching Hospitals NHS Trust (UK)

**Sponsor details**

Beckett Street

Leeds

England

United Kingdom

LS9 7TF

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.leedsteachinghospitals.com/>

**ROR**

<https://ror.org/00v4dac24>

# Funder(s)

## Funder type

Industry

## Funder Name

Asahi Kasei Medical Corporation (Japan)

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2014		Yes	No