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VITAL: VITamin E and Anaemia in dialysis patients in Leeds

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[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
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United Kingdom
LS9 7TF

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 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

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 erythropoeisis 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?
Results article	results	01/03/2014		Yes	No