

Kinetic Oscillation Stimulation (KOS) in chronic hemodialysis: new potential anti-inflammatory treatment

Submission date 26/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/12/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/12/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many patients with end-stage renal (kidney)disease survive because of chronic dialysis. Dialysis does some of the work usually done by the kidneys, such as removing waste products and excess fluid, maintaining safe levels of potassium, sodium and bicarbonate in the blood stream and helping to control blood pressure. However dialysis patients have an increased risk of cardiovascular disease and therefore are at a high risk of premature death. This may be partly due to autonomic dysfunction, whereby the autonomic nervous system (which controls basic bodily functions such as heart rate, breathing rate, body temperature and so on) no longer works properly and chronic inflammation. We want to explore the effects of a non-invasive device 3-4 times weekly on inflammation in adult dialysis patients and potential changes in autonomic dysfunction over a period of 3 months.

Who can participate?

Adult patients undergoing chronic dialysis

What does the study involve?

Participants are treated with the Kinetic Oscillation Stimulation (KOS) device for 10-15 minutes, 3 times a week before their dialysis session. The device is inserted into a nostril with a probe which is then stimulated with a low electric current causing oscillations. The participant feels a vibrating sensation. We look for evidence of inflammation and assess variations in heart rate at the start and end of the study period.

What are the possible benefits and risks of participating?

Kinetic Oscillation Stimulation(KOS) is safe and has been used in over 100 patients with chronic rhinitis and migraine. The vibrating sensation is not painful but may cause a slight discomfort initially. If KOS does have an anti-inflammatory effect this may benefit the research subjects taking part in the study. However this cannot be guaranteed.

Where is the study run from?

Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to December 2016

Who is funding the study?

1. Stockholm County Council (ALF project) (Sweden)
2. Westman Foundation (Sweden)
3. Martin Rind Foundation (Sweden)

Who is the main contact?

Professor Annette Bruchfeld

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

DIA-CAP version 1

Study information

Scientific Title

Modulation of the Cholinergic Anti-inflammatory Pathway in DIAlysis

Acronym

DIA-CAP

Study objectives

The overall aim of this open-label study is to investigate the effect of a new, non-pharmacological method that may induce changes in autonomic dysfunction in the dialysis setting and thereby influence chronic inflammation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethical review board, Stockholm, 23/04/2014, ref. 2014/538-31/1

Study design

Interventional, single-centre, open-label study.

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic inflammation in chronic dialysis patients

Interventions

We will use the Kinetic Oscillation Stimulation (KOS) device in chronic hemodialysis 3 times weekly during 10-15 minutes prior to the dialysis session. The device is inserted into one of the nostrils with a probe which is then stimulated with a low electric current causing oscillations. The research subject experiences this as a vibrating sensation. Our hypothesis is that this may stimulate the cholinergic anti-inflammatory pathway via the vagus nerve and decrease inflammation in this patient group with underlying chronic inflammation.

Intervention Type

Device

Primary outcome measure

1. Inflammatory markers in serum and in stimulated whole blood during follow-up compared to prior to stimulation.
2. Heart rate variability by EKG (autonomic dysfunction assessment) during follow-up compared to prior to stimulation

Secondary outcome measures

Health assessment questionnaires

Overall study start date

01/01/2014

Completion date

31/12/2016

Eligibility

Key inclusion criteria

All stable adult patients with no age limit undergoing chronic dialysis.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10-12

Key exclusion criteria

Ongoing clinical infection.

Date of first enrolment

24/11/2014

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska University Hospital

Stockholm

Sweden

Sponsor information

Organisation

Karolinska University Hospital

Sponsor details

Dept of Renal Medicine, M99
Stockholm
Sweden
14186

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00m8d6786>

Funder(s)**Funder type**

Government

Funder Name

Stockholms Läns Landsting

Alternative Name(s)

Stockholm County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Westman Foundation (Sweden)

Funder Name

Martin Rind Foundation (Sweden)

Results and Publications

Publication and dissemination plan

We will as soon as possible present data from this study at conferences and as articles. However we are now in the early pilot stage and it is too early to present a time-line.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request