ISRCTN49663124 https://doi.org/10.1186/ISRCTN49663124

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

Submission date
26/11/2014

Recruitment status
No longer recruiting

Registration date
04/12/2014

Overall study status
Completed

Last Edited
04/12/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Health assessment questionnaires

Completion date
31/12/2016

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request