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# 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?
Professor Annette Bruchfeld
Annette.bruchfled@ki.se

# Contact information

### Type(s)
Scientific

### Contact name
Professor Annette Bruchfeld

### Contact details
Dept of Renal Medicine, M99
Karolinska University Hospital
Stockholm
Sweden
1186
+46-8-58580000
annette.bruchfeld@ki.se

# 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