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A comparison of intravenous iron and placebo (NaCl) for treatment of Restless Legs Syndrome (RLS)

Submission date 11/02/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/02/2008	**Overall study status** Completed	
Last Edited 28/02/2008	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jan Ulfberg

Contact details
Medical Department
Avesta Hospital
Avesta
Sweden
SE-774 82

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPV-0105

Study information

Scientific Title
A randomised, double-blind, comparative, multi-centre study of intravenous iron and placebo (NaCl) for treatment of Restless Legs Syndrome (RLS)

Study objectives
Is 5 x 200 mg iron sucrose over 3 weeks more effective in the treatment of restless legs than placebo?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital, Uppsala. Date of approval: 13 June 2003 (ref: 03-141)

Study design
Randomised, double-blind, placebo-controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Restless legs syndrome

Interventions
200 mg iron sucrose intravenously 5 times over 3 weeks versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
iron sucrose

Primary outcome measure
International RLS Study Group Rating Scale at 11 weeks

Secondary outcome measures
1. Epworth Sleepiness Scale at baseline, after 3 , 7 and 11 weeks, 5 , 8 and 12 months
2. Incidences and severities of adverse events, assessed after 3 , 7 and 11 weeks, 5, 8 and 12 months
3. To assess the ability of the treatments to correct aberrant haematology and iron status at baseline, after 3 , 7 and 11 weeks, 5 , 8 and 12 months

Overall study start date
26/06/2003

Completion date
22/06/2005

Eligibility

Key inclusion criteria
1. Aged 18-70 years
2. RLS defined by four cardinal criteria
3. Ten points or more on the International RLS (IRLS) Study Group Rating Scale
4. S-ferritin below 45 µg/L, and with folic acid and vitamin B12 within reference values
5. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Treatment with any of the following:
1.1. Psychopharmacological treatment with antidepressive and dopaminergic agents, sedatives, anticonvulsants and/or pain relievers, i.e. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or stronger, during the preceding 2 weeks. This was changed in study protocol clarification number 2 to "...i.e. with the exception of NSAIDs - during the last 2 weeks".
1.2. Calcium antagonists, antihistaminic or antiemetic drugs during the preceding 2 weeks.

1.3. Iron administration during the preceding 2 months
1.4. Nutritional supplements or natural pharmaceuticals containing iron
1.5. Antiepileptics
1.6. Vitamin B12 or folic acid
2. Presence of clinically significant disease/dysfunction, which in the opinion of the investigator should disqualify the patient from this study, such as asymptomatic intestinal bleeding
3. Patients suffering from obstructive sleep apnoea syndrome
4. S-creatinine >130 µmol/L
5. Positive result of pregnancy test
6. Breast-feeding women
7. Contraindications for iron sucrose

Date of first enrolment
26/06/2003

Date of final enrolment
22/06/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Medical Department
Avesta
Sweden
SE-774 82

Sponsor information

Organisation
Renapharma AB (Sweden)

Sponsor details
Box 938
Uppsala
Sweden
SE-751 09

Sponsor type
Industry

Website
http://www.renapharma.se

ROR
https://ror.org/03x49ea82

Funder(s)

Funder type
Industry

Funder Name
Renapharma AB (Sweden)

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