

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	<input type="checkbox"/> Prospectively registered
Registration date 15/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/02/2008	Condition category Nervous System 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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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