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

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

## 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

## Protocol serial number

**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  $\times$  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

## Study type(s)

Treatment

## 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(s)

International RLS Study Group Rating Scale at 11 weeks

## Key secondary outcome(s))

- 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

## 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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

70 years

#### Sex

Αll

## 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)

#### **ROR**

https://ror.org/03x49ea82

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Renapharma AB (Sweden)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No