ISRCTN82469428 https://doi.org/10.1186/ISRCTN82469428

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

**Submission date**
11/02/2008

**Registration date**
15/02/2008

**Last Edited**
28/02/2008

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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## 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 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

### 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
All

### 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 | Yes |