

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

<b>Submission date</b> 11/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/02/2008	<b>Condition category</b> 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

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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