PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

An Interventional, Single-site, Open-label, Four-group, Single-dose Study Investigating the Pharmacokinetic Properties of Nalmefene in Subjects With Renal Impairment (Mild, Moderate, or Severe) and in Healthy Subjects

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

To investigate if renal impairment will have an impact on the pharmacokinetics of nalmefene

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00006361**
- Date of Registration in DRKS: **2014/09/03**
- Date of Registration in Partner Registry or other Primary Registry: **2013/08/22**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01934166 (ClinicalTrials.gov)**
- Sponsor-ID: **15084A (H. Lundbeck A/S)**
- Other Secondary-ID: **2012-005711-53**

Health condition or Problem studied

- Free text: **Renal Impairment**
- ICD10: **N18 - Chronic kidney disease**

Interventions/Observational Groups

- Arm 1: **Drug: Nalmefene 18 mg**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **[---]***
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- For nalmefene and the metabolite nalmefene 3-O-glucuronide: area under the plasma concentration-time curve from zero to infinity (AUC0-inf); time frame: Up to 120 hours post-dose
- For nalmefene and the metabolite nalmefene 3-O-glucuronide: area under the plasma concentration-time curve from zero to time t (t being the time for last quantifiable concentration) (AUC0-t); time frame: Up to 120 hours post-dose
- For nalmefene and the metabolite nalmefene 3-O-glucuronide: maximum observed concentration (Cmax); time frame: Up to 120 hours post-dose
- For nalmefene and the metabolite nalmefene 3-O-glucuronide: nominal time corresponding to the occurrence of Cmax (tmax); time frame: Up to 120 hours post-dose
- For nalmefene and the metabolite nalmefene 3-O-glucuronide: apparent elimination half life in plasma (t½); time frame: Up to 120 hours post-dose
- For nalmefene and the metabolite nalmefene 3-O-glucuronide: renal Clearance (CLR); time frame: Up to 120 hours post-dose
- For nalmefene: oral clearance for nalmefene defined as dose/AUC0-inf (CL/F); time frame: Up to 120 hours post-dose
- For nalmefene: apparent volume of distribution for nalmefene (Vz /F); time frame: Up to 120 hours post-dose

- For the metabolite nalmefene 3-O-glucuronide: metabolic ratio (MR) defined as AUC0-inf,metabolite/AUC0-inf,parent; time frame: Up to 120 hours post-dose

Secondary Outcome

- Safety and tolerability; time frame: Up to 10 days; Number of adverse events

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **DE801, Munich**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/07/31**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

- Healthy young subjects and subjects with renal impairment with a Glomerular Filtration Rate (GFR) of 50-80 ml/min/1.73m2, 30-<50 ml/min/1.73m2, <30 ml/min/1.73m2 will be included in the study.

- The subjects must have a BMI between 19 and 32 kg/m2.

Exclusion criteria

- The subject has a history of renal transplant or is undergoing dialyse treatment.

- The subject is, in the opinion of the investigator, unlikely to comply with the protocol or is unsuitable for any reason.

Other inclusion and exclusion criteria may apply.

Addresses

■ **Primary Sponsor**

H. Lundbeck A/S

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 3
- Last processed date by ClinicalTrials.gov: 2014/11/27

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*