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

Trial Description

Title

A Phase 1 Study to Evaluate the Pharmacokinetics of ITCA 650 in Subjects With Mild and Moderate Renal Impairment Compared to the Pharmacokinetics of Subjects With Normal Renal Function

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

A Phase 1 study to evaluate the pharmacokinetics of ITCA 650 in subjects with mild and moderate renal impairment compared to the pharmacokinetics of subjects with normal renal function

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00008819**
- Date of Registration in DRKS: **2015/08/12**
- Date of Registration in Partner Registry or other Primary Registry: **2014/11/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02320045 (ClinicalTrials.gov)**

- Sponsor-ID: **ITCA 650 CLP-109 (Intarcia Therapeutics)**

Health condition or Problem studied

- Free text: **Renal Insufficiency**
- ICD10: **N19 - Unspecified kidney failure**

Interventions/Observational Groups

- Arm 1: **Drug: ITCA 650 (Exenatide in osmotic mini pump)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- 24-h Area under the Curve at steady state (AUCt,ss); time frame: Approximately 67 Days

Secondary Outcome

- Rate of adverse events; time frame: Approximately 67 Days
- Severity of adverse events; time frame: Approximately 67 Days
- Safety laboratory parameters; time frame: Approximately 67 Days
- Vital signs; time frame: Approximately 67 Days
- Electrocardiogram; time frame: Approximately 67 Days
- Physical exam; time frame: Approximately 67 Days

Countries of recruitment

- US **United States**
- DE **Germany**

Locations of Recruitment

- **Study Site, Kiel**
- **Study Site, Mannheim**
- **Study Site, Moenchengladbach**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/11/30**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **25 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- Body mass index between 22 and 40 kg/m²

- Subjects meeting pre-defined estimated glomerular filtration rate criteria and creatinine clearance rate

- Normal (≥90 mL/min/1.73 m2)

- Mild (60-89 mL/min/1.73 m2)

- Moderate (45-59 mL/min/1.73 m2)

- Moderate (>30-44 mL/min/1.73 m2)

Exclusion criteria

- **History of acute metabolic complications**
    - **Uncontrolled Hypertension**
    - **History of Hypersensitivity to Exenatide**
    - **Cardiovascular Disease**
    - **History of Acute or chronic pancreatitis**
    - **Personal or family history of Multiple endocrine neoplasia type 2**
    - **History of Medullary thyroid cancer**
    - **Severe renal failure, End stage renal disease or dialysis**

Addresses

■ **Primary Sponsor**

Intarcia Therapeutics

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

■ **Contact for Scientific Queries**

Michelle Baron, MD, FACE

Telephone: **[---]***
Fax: **[---]***
E-mail: **clinicaltrials at intarcia.com**
URL: **[---]***

■ **Contact for Public Queries**

Michelle Baron, MD, FACE

Telephone: **[---]***
Fax: **[---]***
E-mail: **clinicaltrials at intarcia.com**
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 ongoing**
- 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: 2
- Last processed date by ClinicalTrials.gov: 2015/06/17

** 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.*