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

Trial Description

Title

Study to Investigate Efficacy and Safety Equivalence of OsvaRen® Tablets and OsvaRen® Granules

Trial Acronym

OsvaRen-NEW

URL of the trial

[---]*

Brief Summary in Lay Language

Phosphate binders are crucial to the control of elevated phosphate levels in patients with chronic kidney disease. With the new formulation of granules the pill burden of patients is sought to be reduced.

This study is about efficacy and safety of the new drug formulation and compares it to the "old" formulation which are film-coated tablets.

Brief Summary in Scientific Language

The study is aimed at demonstrating the therapeutic equivalence of both products, i.e. granules versus tablets.

Secondary objectives are: Comparing both preparations with regard to the number of patients reaching serum phosphate levels < 1.76 mmol/L and the difference in serum phosphate levels between the first and last visit under each treatment. Furthermore, it is the aim of this study to evaluate the safety profile of OsvaRen® granules in comparison to OsvaRen® tablets. Especially serum calcium, magnesium, and PTH are of interest.

Organizational Data

- DRKS-ID: **DRKS00006364**
- Date of Registration in DRKS: **2014/09/08**
- Date of Registration in Partner Registry or other Primary Registry: **2013/12/20**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02027662 (ClinicalTrials.gov)**
- Sponsor-ID: **RP-OSV-02-D (Fresenius Medical Care Deutschland GmbH)**

Health condition or Problem studied

- Free text: **Hyperphosphatemia**
- Free text: **Chronic Kidney Disease**

Interventions/Observational Groups

- Arm 1: **Drug: Osvaren Granules**
- Arm 2: **Drug: Osvaren film-coated tablets**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Factorial**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Non-inferiority of phosphate control by granules versus tablets. Serum

phosphate levels will be measured for the primary outcome.; time frame: After 4 weeks of treatment time

Secondary Outcome

- Number of patients reaching serum phosphate levels < 1.76 mmol/L. this study to evaluate the safety profile of OsvaRen® granules. in comparison to OsvaRen® tablets. Especially serum calcium, magnesium, and PTH are of interest.; time frame: Between the first and last visit under each treatment i.e. 4 weeks

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **RWTH University Hospital, Dpt for Nephrology, Aachen**
- **Nephro-Studien GbR am Klinikum Erfurt, Erfurt**
- **Dialysezentrum, Flensburg**
- **Nephrocare Hamburg-Barmbek GmbH, Hamburg**
- **Dialysezentrum, Hannover**
- **Dialysezentrum, Kiel**
- **Dialysezentrum, Magdeburg**
- **Dialysezentrum, Minden**
- **Dialysezentrum, Solingen**
- **Dialysezentrum, Velbert**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
-

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Minimum Age: **18 Years**

- Maximum Age: **80 Years**

Additional Inclusion Criteria

Inclusion Criteria:

- Signed written informed consent form is obtained prior to starting the screening visit

- Male and female patients 18-80 years of age with dialysis dependent renal failure (CKD 5D)

- Patients have been on 3x/week in-centre renal replacement therapy for at least 2 months on either low-flux or high-flux HD or OL-

/HDF

- Prescribed haemodialysis session duration is ≥ 4 hours

- spKt/V ≥ 1.20 according to last in-centre measurement prior the study enrolment

- Patients have been on OsvaRen® tablets for at least 12 weeks as sole phosphate binder and the titration phase has been completed according to physician´s discretion

- Patients are able to take the study medication as prescribed particularly OsvaRen® stickpacks

- Patients are willing to stop any calcium, magnesium or vitamin D containing supplements

- Patients are willing to maintain their typical diet with regards to phosphate uptake for the time of the study

- Patients are willing to comply with the study protocol

Exclusion criteria

Exclusion criteria

- Pregnant women (by blood ß-hCG pregnancy test) or women breast-

feeding or unwilling to use contraceptive measures during the entire course of the study or

- Patients with a life expectancy shorter than the planned duration of the study or

- Patients with any acute or chronic severe disease potentially interfering with study outcomes or

- Patients with PTH levels > 800 ng/l or

- Patients who participated in an interventional clinical study during the preceding 30 days or

- Patients suffering from any other, not mentioned condition which could interfere with the patient's ability to comply with the study or

- Patients who previously participated in the same study are excluded from the study

Addresses

■ **Primary Sponsor**

Fresenius Medical Care Deutschland GmbH

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

■ **Contact for Scientific Queries**

University Aachen
Jürgen Floege, MD

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

■ **Contact for Public Queries**

Frank M Laukhuf, MD

Telephone: **+496172609**

Contact for Public Queries

Frank M Laukhuf, MD

Telephone: **+496172609**
Fax: **[---]***
E-mail: **frank.laukhuf at fmc.ag.com**
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

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: 60
- 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.*