EFFICACY, TOLERABILITY AND SAFETY OF AN ORAL ENZYME COMBINATION VS. DICLOFENAC IN OSTEOARTHRITIS OF THE KNEE – RESULTS OF AN INDIVIDUAL PATIENT-LEVEL POOLED RE-ANALYSIS OF DATA FROM SIX RANDOMIZED CONTROLLED TRIALS

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Study Finalised

Administrative details

EU PAS number

EUPAS12247

Study ID

12248

DARWIN EU® study

No

Study countries

Germany

Study description

Individual patient-level pooled re-analysis of patient-reported data from prospective, randomized, double-blind parallel-group studies in adult patients with moderate to severe OA of the knee treated for at least 3 weeks with OEC or DIC. Appropriate trials will be identified with a systemic literature and database research. Data will be extracted from the original case report forms and re-analysed by a blinded evaluation committee. Primary endpoint is the improvement of Lequesne´s algofunctional index (LAFI) score at study end vs. baseline. Secondary endpoints address LAFI response rates, treatment-related pain intensity changes, adverse events and laboratory parameters.

Study status

Finalised

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/01/2014

Actual: 07/01/2014

Study start date

Planned: 01/07/2015

Actual: 06/07/2015

Data analysis start date

Planned: 03/08/2015

Actual: 03/08/2015

Date of final study report

Planned: 31/12/2015

Actual: 29/01/2016

Sources of funding

- Other

More details on funding

IFNAP, German Pain Association

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Not applicable

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Aim of this study is to evaluate the efficacy and safety/tolerability of OEC vs. DIC for adult patients suffering from OA of the knee.

Study drug and medical condition

Medicinal product name, other

Wobenzym

Study drug International non-proprietary name (INN) or common name

DICLOFENAC

Medical condition to be studied

Osteoarthritis

Population studied

Short description of the study population

Adult patients with moderate to severe osteoarthritis of the knee treated for at least 3 weeks with oral enzyme combination or diclofenac.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Osteoarthritis patients

Estimated number of subjects

700

Study design details

Outcomes

Primary efficacy criteria are the treatment contrasts for LAFI improvement at study end compared to baseline within both treatment groups . The primary efficacy endpoint is the absolute LAFI change vs. baseline. Secondary endpoints address LAFI response rates, treatment-related pain intensity changes, adverse events and laboratory parameters.

Data analysis plan

All efficacy, safety and tolerability analyses will be done in form of a one-stage approach for the whole patient sample, which allows to adjust for any heterogeneity among the included studies. For between groups’ comparisons of continuous/categorical variables Student´s t / Pearson´s Chi2 tests will be used. For within group (e.g. pre-post) comparisons paired samples t-tests wi be performed. All statistical tests arecarried out using a 2-sided significance level of 0.05 and based on a Holm-Bonferroni approach to counteract the problem of multiple comparisons.An additional two-stage approach will be performed as

formal meta-analyses for the primary efficacy endpoint and both efficacy populations evaluated (ITT and PP) to quantify the amount of heterogeneity between included studies. Mean Difference (MD) grounds on analyses of covariance (outcome measures adjusted for baseline LAFI scores, equality: MD = 0.0, superiority: MD <0.0, inferiority MD >1.0).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Individual patient-level data meta-analysis of randomized controlled trials comparing an oral enzyme combination (OEC) vs. diclofenac in adult patients suffering from osteoarthritis of the knee.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No