Prospective non-interventional investigation to evaluate the long-term safety and linked efficacy of the three-dimensional autologous chondrocyte implantation product in paediatric patients from 15 to less than 18 years of age treated with the product (cod16 HS17 paed)

First published: 09/01/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8273

Study ID

35961

DARWIN EU® study

No

Study countries

Germany

Study description

This is a company-sponsored national, open-label, multicentre, non-interventional study in a cohort of adolescent outpatients combining a retrospective data collection and current evaluation of health status by physical examination and validated patient and physician’s questionnaires.Following Directive 2006/1901 the development auf co.don chondrosphere® in paediatric population was discussed with the paediatric committee (PDCO) and a paediatric investigation plan (PIP) was developed. In the context of this PIP, the company is now gathering further safety and linked efficacy data of paediatric patients who have been treated with co.don chondrosphere®. The overall research goal is to assess the long-term safetyand linked efficacy of the three-dimensional autologous chondrocyte implantation product co.don chondrosphere® (ACI-M) in paediatric patients from 15 to less than 18 years of age at the time of implantation.

Study status

Finalised

Research institutions and networks

Institutions

Dr. Ruhnau

Multiple centres: 20 centres are involved in the study, various centres across Germany, Germany

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Klaus Ruhnau

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/08/2014

Actual: 25/08/2014

Study start date

Planned: 30/03/2015

Actual: 27/04/2015

Data analysis start date

Planned: 01/02/2016

Actual: 01/02/2016

Date of interim report, if expected

Planned: 30/09/2016

Actual: 15/09/2016

Date of final study report

Planned: 30/06/2020

Actual: 18/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CO.DON AG

Study protocol

cod16 HS17 paed_Anlage 1_Observational Plan_V1_09Oct14.pdf (869.05 KB)

05_cod16 HS17 paed_OP_V1_Amendment 2.pdf (493.79 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall research goal is to assess the long-term safety and linked efficacy of the three-dimensional autologous chondrocyte implantation product co.don chondrosphere® (ACI-M) in paediatric patients from 15 to less than 18 years of age at the time of implantation. Primary safety parameter is treatment failure rate.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Open-label, multicentre surveillance study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M09AX02) chondrocytes, autologous

chondrocytes, autologous

Medical condition to be studied

Cartilage injury

Population studied

Short description of the study population

Male or female patients aged ≥15 years but <18 years at the time of implantation, who had undergone treatment with co.don chondrosphere®, with the treatment administered between 1 and 8 years before enrolment into the study.

Patients who meet the following criteria can be considered for inclusion into the investigation:

1. Male or female patients being at least 15 but less than 18 years of age at the time of implantation

2. Treatment with co.don chondrosphere® until December 2011

3. Treatment is conducted max. 8 years before enrolment

4. Written informed consent has been obtained.

Exclusion criteria

1. There are no specific exclusion criteria in this non-interventional study.

Age groups

- Adolescents (12 to < 18 years)

Estimated number of subjects

80

Study design details

Outcomes

Treatment failure rate of autologous chondrocyte implantation product co.don chondrosphere®. For all patients (FAS):- Incidence of surgical treatments - Pain, knee function (measured by the KOOS)- QoL as measured by the KOOS and IKDC Subjective Knee Evaluation Form- Global patient assessment of treated knee measured by IKDC Subjective Knee Evaluation Form and modified Lysholm Knee ScoringFor patients that undergo physical examinations:- Average time to treatment failure

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Data analysis plan

All variables will be analysed in an exploratory manner with appropriate descriptive statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles and maximum).An additional subgroup analysis for patients with closed epiphyseal growth plate, patients with open epiphyseal growth plate, and patients with this information being missing, respectively, is planned.Data will be compared to

the results for adult data of patients from 18 to less than 35 years of age.Statistical analyses will be performed using validated statistical software. (e.g. SAS, SAS Institute Inc.)All statistical details including calculated variables and proposed format and content of tables will be detailed in the statistical analysis plan (SAP).

Documents

Study results

2020-06-23_Synopsis_Final Report.pdf (489.65 KB)

Study publications

Hoburg A, Löer I, Körsmeier K, Siebold R, Niemeyer P, Fickert S, Ruhnau K. Matr...

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

Prospective patient-based data collection, 1. Patient Questionnaire2. Information of patient medical-record 3. if applicable, physical examination

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

Unknown