The Effectiveness and Safety of Single 6ml Hyaluronic Acid Intra-articular Injection (Suplasyn® 1-shot) in Managing Symptomatic Primary Osteoarthritis of the Knee in Real-life Practice: ESSIK Survey

First published: 27/11/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS11707

Study ID

28693

DARWIN EU® study

No

Study countries

Croatia

Czechia

Egypt

Slovenia

Study description

The current study is designed to assess the effectiveness and safety of one 6ml injection of Suplasyn® 1-shot in a 26-week, international, multicenter, non-interventional observational study of patients recommended with a single intra-articular 6ml injection for the treatment of knee osteoarthritis. The intention is to assess the efficacy and safety of the treatment in real-life practice. Our primary target is to obtain and verify long-term outcomes from a naturalistic primary care experience.Rationale for using viscosupplementation is to restore the protective viscoelasticity of synovial hyaluronic acid, decrease pain and improve mobility. Immediate benefit of viscosupplementation is the relief of pain while long-term benefits results are believed to include the return of joint mobility by the restoration of trans-synovial flow and the metabolic and rheological homeostasis of the joint (31). Short duration of HA within the joint does not fully explain the indisputable long-term clinical efficacy seen in practice (32).In this case, it is appropriate to evaluate, under real-life conditions, the short-term and long-term effectiveness of a single injection of Suplasyn® 1-shot 6ml intra-articular injections and to how the extended treatment regime may impact patient satisfaction or treatment safety.

Study status

Finalised

Research institutions and networks

Institutions

Krnov Hospital

Multiple centres: 21 centres are involved in the study

Contact details

Study institution contact

Pavel Martinek clever@recerca.com

Study contact

clever@recerca.com

Primary lead investigator

Pavel Martinek

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/05/2014

Study start date

Actual: 16/06/2014

Date of final study report

Planned: 01/12/2016

Actual: 27/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mylan Institutional International

Study protocol

ESSIK Protocol_Adapted_130614.pdf (266.04 KB)

Regulatory

Was the study required by a regulatory body?

No

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 intention is to assess the efficacy and safety of the treatment in real-life practice. Our primary target is to obtain and verify long-term outcomes from a naturalistic primary care experience.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Cases Report

Study drug and medical condition

Medicinal product name, other

Suplasyn 1-shot

Medical condition to be studied

Osteoarthritis

Population studied

Short description of the study population

Patients over 18 years old with Primary Knee Osteoarthritis (Kellgren’s grades I to III) without effusion.

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

Knee Osteoarthritis patients

Estimated number of subjects

300

Study design details

Outcomes

To assess changes in clinical outcome of patients with OA recommended with a single injection with Suplasyn® 1-shot viscosupplementation for knee OA during a 26 weeks follow-up. - To evaluate the safety profile and adverse events (AEs) of Suplasyn® 1-shot injection.- To evaluate the concomitant consumption of permitted rescue medications (analgesics, NSAIDS) throughout the study.- To evaluate characteristics of the beneficiary population (Intended to treat).

Data analysis plan

The primary efficacy endpoint is the change from baseline in the Oxford knee score assessing the function of the OA knee and the change from baseline in the patient-rated knee OA pain assessment at 4 and 26 weeks.Both scores obtained with the Oxford Knee Score and Pain VAS will be registered at 1 and 6 months following viscosupplementation of the knee.Secondary objectives correspond to the evaluation of the safety profile and adverse events (AEs) of Suplasyn® 1-shot 6ml injection, assessment of concomitant consumption of permitted rescue medications (analgesics, NSAIDs) throughout the study and the known the characteristics of the beneficiary population (intend-to-treat).Continuous variables will be expressed as mean ± Standard Deviation (SD) while categorical binary variables will be presented as percentages.Both primary and secondary objectives will be analyzed with tests for repeated measures to determinate the evolution of the variables throughout study visits.

Documents

Study results

EUPAS11707-28691.pdf (4.55 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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