

## Lay Protocol Synopsis

<b>Lay language title:</b>	An observational study with Structum® in osteoarthritis
<b>Full study title:</b>	A Prospective Non-Interventional Study on STRUctum® in Adult Patients with oSTeoarthritis - TRUST
<b>Registry number:</b>	NCT06623773

### 1 What is the purpose of the study?

Osteoarthritis or arthrosis is a disorder that can affect any joint of the body, like the knees. Osteoarthritis may result in pain, stiffness and loss of movement. Many treatments are available to reduce pain due to osteoarthritis.

Among these treatments, there are drugs termed chondroprotective. Chondroprotective drugs help protect cartilage by slowing down cartilage breakdown and helping it regenerate. They improve symptoms of osteoarthritis like pain and stiffness. Chondroitin sulfate is a natural chondroprotective substance present in the joints of the body. Structum® is a drug containing chondroitin.

To date, no real-world studies have been conducted to describe the burden associated with osteoarthritis in people treated with chondroitin. This study aims to understand how people live with knee osteoarthritis and how chondroitin sulfate may help improve their daily life.

## **2 What are the objectives of the study and how are they evaluated?**

The primary objective was to describe the characteristics of the people treated with Structum<sup>®</sup>. The severity of their knee osteoarthritis was also described. The severity was evaluated using a questionnaire named Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

The secondary objectives were to describe over 6-month follow-up:

- The severity of the knee osteoarthritis
- The burden associated with knee osteoarthritis using a questionnaire named BONE'S
- The general health and quality of life using a questionnaire named SF-12
- How many people were taking Structum<sup>®</sup>
- How people were satisfied with Structum<sup>®</sup>

## **3 How was the study conducted?**

The study was an observational, real-world study conducted over a 6-month period.

Observational means doctors do not change the usual care of the participants. They only collect information during usual visits. No extra tests or visits were required for the study. Participants usually have 2 follow-up visits: after 3 months and after 6 months. People had to fill out 4 questionnaires at each visit related to the severity of the disease, its burden, general health, quality of life, and their level of satisfaction with Structum<sup>®</sup>.

This study was carried out done in people for whom Structum<sup>®</sup> was prescribed by their doctor.

## **4 Who can take part in the study?**

The study took place in Poland.

The following people that fulfilled the following criteria could participate in the study:

- Adults aged 50 to 85 years (because knee osteoarthritis is more common in this age group)
- Diagnosed with knee osteoarthritis
- Treated with Structum<sup>®</sup>
- With dosage of osteoarthritis pain medication stable at least one week prior to study entry, if any
- Participants able to visit the health care facility
- Who agreed to participate in the study

## **5 What are the study treatments and how are they administered?**

People included in the study took Structum® daily prescribed by their doctor according to local clinical practices. The prescription followed the instructions for doctors on how to use safely Structum®.

**6**

**Ethical considerations**

This study was conducted according to ethical considerations and followed the rules for conducting such a study. The study was approved by health authorities before it started. People signed a consent form to confirm they agreed to participate.

**7**

**What are the possible benefits and risks in taking part in the study?**

People were prescribed Structum® daily by their doctor, according to the usual routine practice. People received information about Structum® by their doctor. Participation in this study meant that people had 4 questionnaires to complete at each visit. Answering questionnaires may help doctors understand how osteoarthritis affects daily life.

Taking part in this study did not require the participant to do anything additional like special extra test or visit. There were no additional risks or direct benefits for participants. However, results of this study may contribute to improving the understanding of osteoarthritis.