established.¹ Selective inhibitors of COX-2 are thought to reduce pain, fever and inflammation without causing the gastrointestinal or renal injury associated with inhibition of COX-1.² SVT-2016 is a new COX-2 inhibitor being developed for the treatment of pain and inflammation associated with osteoarthritis and rheumatoid arthritis.

Objectives Evaluate the safety and tolerability of rising doses (16 mg, 32 mg and 64 mg) of SVT-2016, in healthy male volunteers. In addition, the pharmacokinetics (PK) of SVT-2016 following a single oral dose was examined.

Methods Three groups of 6 healthy male volunteers, aged 23–43 years, were exposed to a single oral dose of SVT-2016 or matching placebo (Group 1: 16 mg SVT-2016, Group 2: 32 mg SVT-2016 and Group 3: 64 mg SVT-2016). For each group, subjects were randomised to receive either SVT-2016 or matching placebo (2:1 active to placebo). All volunteers provided informed written consent prior to participation. The study was approved by the Simbec Independent Ethics Committee. Following administration of SVT-2016, blood samples were taken for the determination of plasma SVT-2016 levels at the following time points: Pre-dose, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 16, 24, 36 and 48 h post dose. Vital signs were measured and a 12-lead ECG performed throughout the 48 h post dose. Continuous ECG monitoring took place until 4 h after dosing. Laboratory safety tests were conducted prior to dosing and at 24 h and 48 h post dose. Adverse events were monitored throughout the study. Validated LCMS method was used for the determination of plasma SVT-2016 concentrations.

Results There were no clinically significant changes in vital signs, ECG or laboratory safety tests during the study. A total of three adverse events were recorded (2 events of mild headache and 1 event of mild dizziness). No serious or severe adverse events were recorded. All events were considered to be mild in severity. The pharmacokinetic profile obtained following a single oral dose of SVT-2016 demonstrates that, SVT-2016 was absorbed in a dose dependent manner, C_{max} increasing with increasing dose level administered. This peak plasma concentration occurs at approximately 1.7 h (range: 1.5 h ? 1.9 h) following administration of SVT-2016, suggesting a rapid onset of action. The elimination half-life of SVT-2016 appears to increase with increasing dose level and would support the suitability of this compound for the treatment of patients with osteoarthritis and rheumatoid arthritis.

Conclusion SVT-2016 was considered to be safe and well tolerated at the dose levels investigated. The PK obtained favour the development of SVT-2016 as a novel COX-2 inhibitor for the treatment of pain and inflammation associated with osteoarthritis and rheumatoid arthritis. To further examine the safety, tolerability and PK of SVT-2016, it is proposed that further dose levels be investigated.

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SAT0083 ULTRASONOGRAPHIC EVIDENCE OF INTRA-ARTICULAR INJECTIONS IN THE HIP

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10.1136/annrheumdis-2001.458

Background In order to validate intra-articular medical treatment of osteoarthritis in the hip joints it is imperative to have documentation of the correct placement of the injection.

Radiographic methods imply a radiation load, while ultrasound (US) is harmless.

Objectives Our goal was to evaluate the use of US as guidance when performing injections in osteoarthritic hips using air as contrast medium.^{1–3}

Methods A total of 30 injections were given to 11 Patients with hip-osteoarthritis (ACR criteria)(Mean age 60 years (Range 44–86)).

The femoral head and neck was scanned with a 8–13 MHz linear transducer.

The probe was placed below the inguinal ligament in parallel with the axis of the femoral neck.

Placement of a gauge 21 needle into the hip joint (anterior/inferior capsule below the femoral head) was monitored with a B mode (grey scale) scanning allowing a continuous visual guidance.

Preceding the treatment, a small (0,5–2 ml) amount of atmospheric air was injected.

Results The position of the needle was evident on the screen in all cases. The injections of air into the joint was demonstrated in 29 cases presenting a small hyperechoic brim inside the joint capsule. However, in one case in spite of a seemingly correct placement of the needle the hyperechoic air brim was clearly positioned outside the joint. Placement of the needle was subsequently corrected.

Still picture of the setting as documentation revealed the presence of air without difficulty, however the needle tended to be less recognisable when not in motion.

Conclusion The sole use of grey scale US as guidance device gives a good view of the intra-articular placement of a needle. However use of air as US contrast before an injection or aspiration, enhances the precision and allows photographic documentation of the set-up.

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SAT0084 DEVELOPMENT AND INITIAL PSYCHOMETRIC VALIDATION OF THE ARTHRITIS TREATMENT SATISFACTION QUESTIONNAIRE (ARTS)

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10.1136/annrheumdis-2001.459

Background

Objectives To develop and examine the reliability and validity of a questionnaire assessing patient satisfaction with their osteoarthritis treatment.

Methods Item generation: Semi-structured interviews were performed among 20 French patients (6 suffering from arthritis of the knee, 6 of the hip and 8 of the hand), and 10 clinicians (5 rheumatologists and 5 general practitioners (GPs)). Interviews were recorded, transcribed and analysed. The first version of the questionnaire was produced in French and reviewed by 5 rheumatologists and 5 GPs. Content validity and cognitive debriefing