Observational Prospective Study on 2-Chloroprocaine Hydrochloride 1% Safety in Intrathecal Anaesthesia

First published: 25/11/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33371

EU PAS number

EUPAS16398

Study ID

33371

DARWIN EU® study

No

Study countries

☐ Belgium

☐ France

☐ Germany

☐ Italy

Study description

The present study aims to evaluated in 380 patients the relationship between spinal block with 1% solution of 2-chloroprocaine hydrochloride and the onset of all possible neurological adverse events, with particular attention to Transient Neurological Symptoms (TNS) and Cauda Equina Syndrome (CES).This is a prospective, observational, multicenter study involving 7 different centers distributed in 4 European countries: Italy, France, Belgium and Germany. This observational study is planned to collect data on patients undergoing surgery under intrathecal anesthesia with chloroprocaine hydrochloride, primarily to assess the occurrence of all possible neurological adverse events (with particular attention to TNS and CES).Two follow-up questionnaires are foreseen, at 24 h and 7 days after time of spinal injection (Tsp), to gather all possible neurological complications. About 24 h after surgery (indicated as Tsp), Investigator or a deputy will question patients about neurological symptoms, in particular TNS/CES, and pain not associated to the operation area on the basis of the two follow-up questionnaires and giving a score between 0 to 10 to the pain intensity. All other AEs will also be assessed.

Study status

Finalised

Research institutions and networks

Institutions

Azienda Ospedaliera di Parma - Università di Parma -Dipartimento di Anestesia, Rianimazione e Terapia Antalgica

Department of Anesthesiology and Critical Care Medicine of Lapeyronie University Hospital and Montpellier University Montpellier, France, Rizzoli Hospital Bologna, Italy, Department of Anesthesiology and Critical Care Medicine, Hospital Sint Jozeph Malle, Belgium, Klinik für Anästhesie, Intensivmedizin und Schmerztherapie, Klinikum Westfalen Gmbh Lünen, Germany, Department of Klinik für Anästhesiologie, Intensiv-, Palliativ- und Schmerzmedizin Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil Bochum, Germany, Clinique générale d'Annency - La consultation d'Anesthésie Annecy, France

Contact details

Study institution contact

Elisabetta Donati

Study contact

edonati@sintetica.com

Primary lead investigator

Guido Fanelli

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/02/2013

Study start date

Actual: 26/11/2013

Date of final study report

Planned: 27/05/2017

Actual: 26/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sintetica SA

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

ClinicalTrials.gov Identifier:NCT02067806

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

Data collection methods:

Primary data collection

Main study objective:

The present study aims to evaluate the relationship between spinal block with 1% solution of 2-chloroprocaine hydrochloride and the onset of all possible neurological adverse events, with particular attention to Transient Neurological Symptoms (TNS) and Cauda Equina Syndrome (CES).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational study

Study drug and medical condition

Name of medicine, other

Ampres, Decelex, Clorotekal

Medical condition to be studied

Anaesthetic complication neurological

Population studied

Short description of the study population

Male and female adult patients undergoing spinal anesthesia with chloroprocaine, when the planned surgical procedure was not expected to exceeded 40 minutes.

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)

Estimated number of subjects

380

Study design details

Outcomes

The primary endpoint is the incidence of neurological complications (Transient and Permanent complications, e.g. transient neurological symptoms, arachnoiditis, cauda equina syndrome). Two follow-up questionnaires are foreseen, at 24 h and 7 days after time of spinal injection, to gather all possible neurological complications, with particular attention to TNS and CES. Other endpoints is the incidents of other adverse events (AEs) e.g.: paraesthesia, haemorrhage, headache, micturition/defecation difficulties, tiredness, nausea/vomiting, dizziness, hypotension, bradycardia, Post Dural Puncture Headache (PDPH), epidural haematoma, anterior spinal artery syndrome,meningitis.

Data analysis plan

The main goal will be the incidence of:- Transient Neurologic Symptoms (TNS) at 24 h and 7 days after Tsp- Cauda Equina Syndrome (CES) at 24 h and 7 days after TspThe above analysis will be stratified, if numbers permitted, according to the following age groups: 18-64 and >65 years old.

Documents

Study results

Summary Report_CHL1-01-2012-M.pdf(77.15 KB)

Study publications

Zaric D, Pace NL. Transient neurologic symptoms (TNS) following spinal anaesthe...

Lacasse MA, Roy JD, Forget J, Vandenbroucke F, Seal RF, Beaulieu D, McCormack M...

Camponovo C, Wulf H, Ghisi D, Fanelli A, Riva T, Cristina D, Vassiliou T, Lesch...

Hejtmanek MR, Pollock JE. Chloroprocaine for spinal anaesthesia: a retrospectiv...

Vaghadia H, Neilson G, Lennox PH. Selective spinal anesthesia for outpatient tr...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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