

# 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

### EU PAS number

EUPAS16398

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### Study ID

33371

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### DARWIN EU® study

No

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### Study countries

 Belgium

 France

 Germany

 Italy

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## **Study description**

The present study aims to evaluate 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.

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## **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'Annecy - La consultation d'Anesthésie  
Annecy, France

Contact details

### **Study institution contact**

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Study contact

[edonati@sintetica.com](mailto:edonati@sintetica.com)

### **Primary lead investigator**

Guido Fanelli

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 22/02/2013

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### **Study start date**

Actual: 26/11/2013

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### **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

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## 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

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#### Study type:

Non-interventional study

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#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**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

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**Non-interventional study design, other**

Prospective, observational study

## Study drug and medical condition

**Medicinal product name, other**

Ampres, Decelex, Clorotekal

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**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 exceed 40 minutes.

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## **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)
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## **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.

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## 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)

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### 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...](#)

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## 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No