ISRCTN57987506 https://doi.org/10.1186/ISRCTN57987506

Spinal anaesthesia in adolescent population with 2-chloroprocaine 1% for lower limb procedures of short duration: a prospective, randomised, blind-observer, dose-finding study

Submission date
17/12/2010

Recruitment status
Stopped

Registration date
07/02/2011

Overall study status
Stopped

Last Edited
14/01/2016

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CHL1/01-2010/CH

Study information

Scientific Title
Prospective, blind-observer, dose-finding, randomised, parallel-group, multicentre study to evaluate the dose-effect relationship of spinal block with 1% solution of plain 2-chloroprocaine

in adolescent patients aged 12 to less than 18 years undergoing short-duration elective surgery on the lower limb

Study objectives
Ambulatory surgical procedures are steadily increasing in Europe and USA. The use of short acting local anaesthetic agents such as chloroprocaine permits rapid onset intrathecal anaesthesia for short duration day-case surgery and early recovery profiles, offering the advantage of early home discharge. According to clinical experience, the surgical procedures which could be covered by the short acting chloroprocaine action in the adolescents are mainly short duration operations on the lower limbs in particular orthopaedic procedures.

A prospective, blind-observer, randomised, multicentre clinical study conducted by Fanelli et al in 2007 - 2008 investigated the efficacy of intrathecal plain solution of chloroprocaine 1% (50 mg) versus bupivacaine 0.5% (10 mg) in 120 patients (M/F, aged 18 - 80 years) undergoing elective short-duration (less than 40 minutes) low abdominal surgery (gynaecology and urology) requiring T10 metameric level of sensory block and identical anaesthesia procedures. According to the Authors' conclusions, intrathecal local anaesthesia with 50 mg 1% 2-chloroprocaine provided adequate spinal anaesthesia for low abdomen and lower limb surgery procedures (less than 40 minutes), with significantly quicker achievement of surgical anaesthesia, recovery from anaesthesia and eligibility for home discharge, compared to 10 mg 0.5% bupivacaine, with a more favourable safety profile. Anatomy and physiology of adolescents, including CSF characteristics, are similar to those of adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Comitato Etico Cantonale, Sezione Sanitaria del Dipartimento della Sanità e della Società) pending approval as of 22/12/2010

Primary study design
Interventional

Study design
Interventional prospective blind-observer dose-finding randomised parallel-group multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal anaesthesia

Interventions
Active constituent: 2-chloroprocaine hydrochloride at a concentration of 1%
Chemical name and formula: N-(2-diethylaminoethyl)-4-amino-2-chlorobenzoate C13H20N2O-HCl MW: 307.22
Pharmaceutical form: injectable solution contained in 5 mL glass ampoules
Route of administration: parenteral, via intrathecal injection, at three different single doses: T1 0.206 mg/cm, T2 0.235 mg/cm, T3 0.265 mg/cm.

Test product at the dose of 0.206 mg/cm, 0.235 mg/cm or 0.265 mg/cm will be administered according to the randomisation list, starting from the lowest number to be assigned to the subject in chronological order.

The formulations are to be administered with a midline approach at L3-L4 or L4-L5 interspace, with the patient in sitting or lateral position and the area to be operated distally located, using a Pencil point needle (27 Gauge diameter). The trial medication will be stored at room temperature (15-25°C) in a dry locked place, sheltered from light.

No treatment or placebo used as control. Follow-up will occur for 7 (-1/+2) days.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
2-chloroprocaine

Primary outcome(s)
Comparison of the efficacy of three 2-chloroprocaine dosages (T1 0.206 mg/cm, T2 0.235 mg/cm, T3 0.265 mg/cm) in terms of proportions of subjects who need additional analgesia or rescue general anaesthesia during surgery.

Key secondary outcome(s)
Evaluation of the following parameters for the three doses of 1% 2-chloroprocaine:
1. Time to the first rescue dose during surgery time
2. Time to onset of motor block; the level of motor block is assessed by using the modified Bromage's scale
3. Maximum level of sensory block
4. Time to resolution (Offset) of sensory block to S2
5. Time to resolution of motor block (Bromage score = 0)
6. Time to the first rescue dose after surgery time
7. Time to unassisted ambulation
8. Presence of urinary retention
9. Time to eligibility for home discharge (for day surgery only)

Sensory block will be verified by bilateral Pinprick test using a 20-G hypodermic needle and will be recorded. The quality of spinal block will be verified according to the need for supplementary intravenous analgesics and sedation as follows:
1. Adequate spinal block = neither sedation nor analgesics required to complete surgery
2. Inadequate spinal block = need for additional analgesia (2 µg/Kg mg iv bolus of fentanyl) required to complete surgery
3. Failed spinal block = general anaesthesia required to complete surgery (propofol iv)

Duration of surgery will also be recorded. Motor block will be verified using a modified Bromage scale (0 = no block; 1 = hip blocked; 2 = hip and knee blocked; 3 = hip, knee and ankle blocked).

Completion date
31/10/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Male/female adolescent patients scheduled for short duration (less than 40 minutes) lower limb surgery under spinal anaesthesia
2. Aged 12 to less than 18 years old
3. Body mass index (BMI) between 18 and 32 kg/m2
4. American Society of Anesthesiologists (ASA) physical status I - II
5. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects
6. Ability to co-operate with the Investigator and to comply with the requirements of the entire study
7. Signed written informed consent of the patients prior to inclusion in the study; patient consent has to be expressed prior to the consent of parents/legal guardian
8. Signed written informed consent of parents/legal guardian prior to inclusion in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Lactating females
2. Pregnancy: females who will result positive to the pregnancy test performed at the screening visit
3. Physical findings: clinically relevant abnormal physical findings which could interfere with the objectives of the study
4. Contraindications to spinal anaesthesia
5. History of neuromuscular diseases to the lower extremities
6. ASA physical status III - V
7. Signed written informed consent of parents/legal guardian prior to the patients consent
8. Patients requiring further anaesthesia (i.e. iv propofol)
9. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations ingredients; ascertained or presumptive hypersensitivity to the amide and major

anaesthetics
10. Diseases: ascertained psychiatric and neurological diseases, sepsis, blood coagulation disorders, contraindications to spinal anaesthesia
11. Drug and alcohol: history of drug abuse, history of alcohol abuse, therapeutic use of opioids
12. Assumption of any investigational medicinal product within the previous 60 days before the screening visit

Date of first enrolment
30/03/2011

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
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Sponsor information

Organisation
Sintetica S.A. (Switzerland)

ROR
https://ror.org/0023ccp69

Funder(s)

Funder type
Industry

Funder Name
Sintetica S.A. (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration