Clinical trial results:
Treatment of acute locomotoric pain in the geriatric patient: comparison of effectiveness and safety between step 2 (weak opioids) and step 3 (strong opioids) pain relief of the WHO-ladder.

Summary

EudraCT number	2016-002379-89
Trial protocol	BE
Global end of trial date	06 September 2020

Results information

Result version number	v1 (current)
This version publication date	08 August 2024
First version publication date	08 August 2024
Summary attachment (see zip file)	manuscript (Short-term treatment of acute locomotor pain in older adults_versie060722.docx) full data set (masterproef_ger_PV.pdf) Final Study Report (2016-002379-89_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2016/007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Heymanslaan 10, Gent, Belgium, 9000
Public contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, Bimetra.Clinics@uzgent.be
Scientific contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, Bimetra.Clinics@uzgent.be

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 September 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether there is a difference in effectiveness and safety between two commonly used therapeutic strategies: step 2 versus step 3 of the WHO pain ladder.

Protection of trial subjects:

treatment was based upon good clinical practice
adverse events were monitored and therapy was stopped if necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	25
85 years and over	24

Subject disposition

Recruitment

Recruitment details:

See attachment Final Study Report

Pre-assignment

Screening details:

70 years or older, admitted to the acute geriatric ward and suffering from acute (less than 72 hours) moderate to severe (numeric rating scale (NRS) ≥ 5) locomotor pain on at least one moment on the day of inclusion

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	oxycodone group

Arm description:

patients treated with strong opioids

Arm type	Active comparator
Investigational medicinal product name	oxycodone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

oxycodone extended release (ER) 5mg twice a day, with oxycodone instant release (IR) 5mg as rescue medication in case of breakthrough pain, with a maximum of six times a day

Arm title	tramadol group

Arm description:

patients treated with weak opioids

Arm type	Active comparator
Investigational medicinal product name	tramadol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

tramadol extended release (ER) 50mg twice a day, with tramadol instant release (IR) 50mg as rescue medication in case of breakthrough pain, with a maximum of four times a day

Number of subjects in period 1	oxycodone group	tramadol group
Started	24	25
Completed	24	25

Baseline characteristics

End points

End points reporting groups	
Reporting group title	oxycodone group
Reporting group description: patients treated with strong opioids	
Reporting group title	tramadol group
Reporting group description: patients treated with weak opioids	

Primary: effect on pain	
End point title	effect on pain
End point description: effect on pain, measured by NRS	
End point type	Primary
End point timeframe: 7 days	

End point values	oxycodone group	tramadol group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: NRS				
number (not applicable)	24	25		

Statistical analyses

Statistical analysis title	effect on pain
Comparison groups	oxycodone group v tramadol group
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: daily	
Assessment type	Systematic

Dictionary used	
Dictionary name	naranjo
Dictionary version	1

Reporting groups	
Reporting group title	tramadol group

Reporting group description: -

Serious adverse events	tramadol group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.01 %

Non-serious adverse events	tramadol group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)		
Nervous system disorders			
Convulsions local			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported