



Clinical trial results:

Treatment satisfaction and self-reported symptoms in patients under opioid maintenance therapy

Summary

EudraCT number	2015-002440-13
Trial protocol	AT
Global end of trial date	24 October 2016

Results information

Result version number	v1 (current)
This version publication date	20 November 2020
First version publication date	20 November 2020

Trial information

Trial identification

Sponsor protocol code	OMT-Satisfaction
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020
Public contact	Ao. Univ.Prof. Dr. Sergei Mechtcheriakov, Medical University Innsbruck, Department of Psychiatry, Anichstrasse 35, 6020 Innsbruck, +43 50504 49010, sergei.mechtcheriakov@tirol-kliniken.at
Scientific contact	Ao. Univ.Prof. Dr. Sergei Mechtcheriakov, Medical University Innsbruck, Department of Psychiatry, Anichstrasse 35, 6020 Innsbruck, +43 50504 49010, sergei.mechtcheriakov@tirol-kliniken.at

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	24 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 October 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This clinical trial aims to systematically collect the treatment related data during the standard clinical OMT course including eventual medication switches. The patients on OMT which manifest with medical, psychological and social-environmental reasons for treatment optimization (incl. the switch of OMT-medication) will be systematically monitored during the treatment regarding their addiction-related behavioral parameters, side-effects, compliance parameters and treatment satisfaction. This study aims to investigate to what extent patient's satisfaction with the current OMT treatment influences compliance and outcome.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	01 December 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	8 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial . "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	SROM
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Substitol retard 200 mg
Investigational medicinal product code	
Other name	Morphine Sulfate
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Methadone can be switched to SROM from one day to the other in a ratio of 1:6-8 of the previous methadone dose.

SROM can be commenced 24 hours after the last dose of buprenorphine, at an initial maximum daily dose of 320 mg morphine (maximum 400 mg). The selection of the first SROM dose should be based on a 1:30-50 ratio.

Investigational medicinal product name	Substitol retard 120 mg
Investigational medicinal product code	
Other name	Morphine Sulfate
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Methadone can be switched to SROM from one day to the other in a ratio of 1:6-8 of the previous methadone dose.

SROM can be commenced 24 hours after the last dose of buprenorphine, at an initial maximum daily dose of 320 mg morphine (maximum 400 mg). The selection of the first SROM dose should be based on a 1:30-50 ratio.

Investigational medicinal product name	Compensan retard 300 mg
Investigational medicinal product code	
Other name	Morphinhydrochlorid-Trihydrat
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Methadone can be switched to SROM from one day to the other in a ratio of 1:6-8 of the previous methadone dose.

SROM can be commenced 24 hours after the last dose of buprenorphine, at an initial maximum daily dose of 320 mg morphine (maximum 400 mg). The selection of the first SROM dose should be based on a 1:30-50 ratio.

Investigational medicinal product name	Compensan retard 200 mg
Investigational medicinal product code	
Other name	Morphinhydrochlorid-Trihydrat
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Methadone can be switched to SROM from one day to the other in a ratio of 1:6-8 of the previous methadone dose.

SROM can be commenced 24 hours after the last dose of buprenorphine, at an initial maximum daily dose of 320 mg morphine (maximum 400 mg). The selection of the first SROM dose should be based on a 1:30-50 ratio.

Investigational medicinal product name	Compensan retard 100 mg
Investigational medicinal product code	
Other name	Morphinhydrochlorid-Trihydrat
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Methadone can be switched to SROM from one day to the other in a ratio of 1:6-8 of the previous methadone dose.

SROM can be commenced 24 hours after the last dose of buprenorphine, at an initial maximum daily dose of 320 mg morphine (maximum 400 mg). The selection of the first SROM dose should be based on a 1:30-50 ratio.

Investigational medicinal product name	Methadon
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

Methadon is part of the Opioid maintenance treatment (OMT).

Investigational medicinal product name	Bupensan 8 mg
Investigational medicinal product code	
Other name	Buprenorphinhydrochlorid
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Bupensan is part of the Opioid maintenance treatment (OMT).

Investigational medicinal product name	Bupensan 4 mg
Investigational medicinal product code	
Other name	Buprenorphinhydrochlorid
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Bupensan is part of the Opioid maintenance treatment (OMT).

Investigational medicinal product name	Bupensan 2 mg
Investigational medicinal product code	
Other name	Buprenorphinhydrochlorid
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Bupensan is part of the Opioid maintenance treatment (OMT).

Investigational medicinal product name	L-Polamidon Solution
Investigational medicinal product code	
Other name	Levomethadone hydrochloride
Pharmaceutical forms	Oral solution

Routes of administration	Oral use
Dosage and administration details:	
L-Polamidon Solution is part of the Opioid maintenance treatment (OMT).	
Investigational medicinal product name	Subutex 8 mg
Investigational medicinal product code	
Other name	Buprenorphine
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use
Dosage and administration details:	
Subutex is part of the Opioid maintenance treatment (OMT).	
Investigational medicinal product name	Subutex 2 mg
Investigational medicinal product code	
Other name	Buprenorphine
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use
Dosage and administration details:	
Subutex is part of the Opioid maintenance treatment (OMT).	
Investigational medicinal product name	Subutex 0.4 mg
Investigational medicinal product code	
Other name	Buprenorphine
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use
Dosage and administration details:	
Subutex is part of the Opioid maintenance treatment (OMT).	
Investigational medicinal product name	Suboxone 8 mg/2mg
Investigational medicinal product code	
Other name	Buprenorphine Hydrochloride
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use
Dosage and administration details:	
Suboxone is part of the Opioid maintenance treatment (OMT).	
Investigational medicinal product name	Suboxone 2 mg/0.5mg
Investigational medicinal product code	
Other name	Buprenorphine Hydrochloride
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use
Dosage and administration details:	
Suboxone is part of the Opioid maintenance treatment (OMT).	

Number of subjects in period 1	SROM
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	99999	99999	
Age categorical			
"99999" is a value for 0 participants.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
"99999" is a value for 0 participants.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
"99999" is a value for 0 participants.			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	SROM
Reporting group description: -	

Primary: Treatment satisfaction

End point title	Treatment satisfaction ^[1]
End point description:	

End point type	Primary
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End point timeframe:

N/A

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No subjects were included in this trial, therefore no statistical analyses was done.

End point values	SROM			
Subject group type	Reporting group			
Number of subjects analysed	99999 ^[2]			
Units: ODAS				
number (not applicable)	99999			

Notes:

[2] - "99999" is a value for 0 participats.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

01.12.2015- 24.10.2016

Adverse event reporting additional description:

No patients were included in this trial , therefore no AEs and SAEs were observed.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.03
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Reporting groups

Reporting group title	SROM
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Reporting group description: -

Serious adverse events	SROM		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	SROM		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No subjects were included in this trial, therefore no AEs or SAEs were observed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 February 2016	Slight amendments concerning CRF, insurance and protocol
21 March 2016	Another PI

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants , as it was not possible to fill in "0" for the number of included patients.

Notes: