Clinical trial results:
Clinical trial to evaluate the efficacy and safety of oral Transidose in patients suffering from constipation.

Summary

EudraCT number	2013-002900-15
Trial protocol	DE
Global end of trial date	31 March 2016

Results information

Result version number	v1 (current)
This version publication date	28 June 2020
First version publication date	28 June 2020
Summary attachment (see zip file)	Statistical Report Transidose final (Statistical Report TRANSIDOSE final Clinical Open Study.pdf)

Trial information

Trial identification

Sponsor protocol code	Transidose-GE_01/2013

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Salsarulo Pharma
Sponsor organisation address	8 rue de l'Est, Boulogne-Billancourt, France, 92100
Public contact	Gilles Salsarulo, Salsarulo Pharma, 0033 618920891, gilles.salsarulo@salsapharma.com
Scientific contact	Gilles Salsarulo, Salsarulo Pharma, 0033 618920891, gilles.salsarulo@salsapharma.com

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	07 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2016
Global end of trial reached?	Yes
Global end of trial date	31 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluation of the efficacy and safety of Transidose p.o.

Protection of trial subjects:

If diarrhea develops the dosage has to be reduced. If diarrhea persists, the treatment with Transidose has to be discontinued.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Candidates for the participation in this monocentric clinical trial are male and female patients as of 18 years of age, suffering from constipation with associated symptoms. Indication for inclusion in the study are rare bowel movements (stool frequency less than three times a week) and the fulfillment of the Rome III criteria. Moreover, a colon

Pre-assignment

Screening details:

The study is introduced by a wash-out period of one week. During this period, patients should not use laxatives. Afterwards the two-week active treatment period follows. The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken orally as single dose in the evening

Period 1

Period 1 title	Period 1 - Wash-out
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Transidose

Arm description:

The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken orally as single dose in the evening but not shortly before bedtime.

Arm type	Experimental
Investigational medicinal product name	Transidose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral paste in sachet
Routes of administration	Oral use

Dosage and administration details:

The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken
orally as single dose in the evening but not shortly before bedtime.

Number of subjects in period 1	Transidose
Started	10
Completed	10

Period 2

Period 2 title	Period 2 - Active arm
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Transidose

Arm description:

The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken orally as single dose in the evening but not shortly before bedtime.

Arm type	Experimental
Investigational medicinal product name	Transidose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral paste in sachet
Routes of administration	Oral use

Dosage and administration details:

The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken
orally as single dose in the evening but not shortly before bedtime.

Number of subjects in period 2	Transidose
Started	10
Completed	9
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups

Reporting group title	Period 1 - Wash-out

Reporting group description: -

Reporting group values	Period 1 - Wash-out	Total	
Number of subjects	10	10	
Age categorical 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)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	55.9		
standard deviation	± 11.1	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	0	0	

End points

End points reporting groups

Reporting group title	Transidose
Reporting group description:	
The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken orally as single dose in the evening but not shortly before bedtime.	
Reporting group title	Transidose
Reporting group description:	
The daily dosage during treatment will range between 10 g and 20 g TRANSIDOSE (1 to 2 sachets corresponding to 3.5 to 7 g lactulose), taken orally as single dose in the evening but not shortly before bedtime.	

Primary: Difference of number of spontaneaous evacuation per week

End point title	Difference of number of spontaneaous evacuation per week
End point description:	
End point type	Primary
End point timeframe:	
After 2 weeks of treatment	

End point values	Transidose	Transidose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	9		
Units: Number of spontaneous evacuation per wee				
arithmetic mean (standard deviation)	1.67 (± 0.50)	5.00 (± 1.94)		

Statistical analyses

Statistical analysis title	Wilcoxon test
Comparison groups	Transidose v Transidose
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation

Secondary: Patient's judgement of efficacy

End point title	Patient's judgement of efficacy

End point description:

End point type	Secondary

End point timeframe:

After 2 weeks of treatment

End point values	Transidose			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: 1				
Very good	2			
Good	4			
Moderate	2			
Poor	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Bristol Stool Forms Scale

End point title	Bristol Stool Forms Scale

End point description:

End point type	Secondary

End point timeframe:

After 2 weeks of treatment

End point values	Transidose	Transidose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	9		
Units: 1				
Typ 1	7	1		
Typ 2	1	2		
Typ 3	0	2		
Typ 4	0	1		
Typ 5	0	1		
Typ 6	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
At treatment start, after 1 week of treatment and at final visit (after 2 weeks of treatment)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	AE reporting group

Reporting group description: -

Serious adverse events	AE reporting group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	AE reporting group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	7 / 9 (77.78%)		
occurrences (all)	41		
Discomfort			
subjects affected / exposed	6 / 9 (66.67%)		
occurrences (all)	31		
Excessive straining			
subjects affected / exposed	7 / 9 (77.78%)		
occurrences (all)	36		
Other			

subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 3		
Gastrointestinal disorders Bloating subjects affected / exposed occurrences (all) Bowel movements subjects affected / exposed occurrences (all) Unsatisfactory Defecations subjects affected / exposed occurrences (all)	 8 / 9 (88.89%) 42 1 / 9 (11.11%) 4 8 / 9 (88.89%) 38		

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