Clinical trial results:
Validation Study to Investigate the Effect of T4P1010 treatment in Patients with Osteoarthritic Pain of Knee or Hip.

Summary

EudraCT number	2017-001028-23
Trial protocol	BE FR
Global end of trial date	24 August 2018

Results information

Result version number	v1 (current)
This version publication date	08 September 2019
First version publication date	08 September 2019

Trial information

Trial identification

Sponsor protocol code	T1010-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03174145
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Tools4Patient
Sponsor organisation address	Rue de Bordeaux, 50 - Boîte 17, Jumet, Belgium, 6040
Public contact	Clinical Trial Information, Tools4Patient SA, T1010-01@tools4patient.com
Scientific contact	Clinical Trial Information, Tools4Patient SA, T1010-01@tools4patient.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	23 July 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 August 2018
Global end of trial reached?	Yes
Global end of trial date	24 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the relationship between the patient’s profile (as defined by his/her disease history, personality characteristics, expectations, genetic profile and demographic characteristics) and his/her placebo response, as defined by the analgesic effect measured by Average Pain Score (APS) reduction after a placebo treatment on osteoarthritic (OA) pain of knee or hip.

Protection of trial subjects:

No specific measures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 2017
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	Belgium: 7
Country: Number of subjects enrolled	France: 31
Country: Number of subjects enrolled	United Kingdom: 35
Worldwide total number of subjects	73
EEA total number of subjects	73

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)	36
From 65 to 84 years	37

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients with osteoarthritis (OA) of knee or hip diagnosed since at least 6 months and pain scores reported during the baseline period with a mean APS between 3.6 and 8.4 inclusive

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

No blinding

Arms

Are arms mutually exclusive?	Yes
Arm title	Active Group

Arm description:

Patients received T4P1010 treatment

Arm type	Experimental
Investigational medicinal product name	Cornstarch
Investigational medicinal product code	T4P1010
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

One capsule twice a day, ideally in the morning between 7 and 10 a.m. and in the evening between 6 and 9 p.m

Arm title	Control Group

Arm description:

Patients followed the control procedures, without T4P1010 treatment

Arm type	Control

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Active Group	Control Group
Started	60	13
Completed	60	12
Not completed	0	1
Consent withdrawn by subject	-	1

Period 2	
Period 2 title	End of Treatment (Week 12)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Active Group

Arm description:

Patients received T4P1010 treatment

Arm type	Experimental
Investigational medicinal product name	Cornstarch
Investigational medicinal product code	T4P1010
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

One capsule twice a day, ideally in the morning between 7 and 10 a.m. and in the evening between 6 and 9 p.m

Arm title	Control Group

Arm description:

Patients followed the control procedures, without T4P1010 treatment

Arm type	Control

No investigational medicinal product assigned in this arm

Number of subjects in period 2	Active Group	Control Group
Started	60	12
Completed	56	11
Not completed	4	1
Protocol deviation	4	1

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	73	73	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	64.0		
standard deviation	± 10.4	-	
Gender categorical Units: Subjects			
Female	34	34	
Male	39	39	

End points

End points reporting groups	
Reporting group title	Active Group
Reporting group description: Patients received T4P1010 treatment	
Reporting group title	Control Group
Reporting group description: Patients followed the control procedures, without T4P1010 treatment	
Reporting group title	Active Group
Reporting group description: Patients received T4P1010 treatment	
Reporting group title	Control Group
Reporting group description: Patients followed the control procedures, without T4P1010 treatment	

Primary: Analgesic efficacy (APS)	
End point title	Analgesic efficacy (APS)
End point description: The patient’s change from baseline of pain severity, as measured by the weekly means of the daily APS in the last 24 hours in patients with OA pain of knee or hip during a 12-week treatment therapy period	
End point type	Primary
End point timeframe: Change from baseline during a 12-week treatment therapy period	

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[1]	11[2]	56[3]	11[4]
Units: 11-point NRS scale				
arithmetic mean (standard deviation)	5.04 (± 1.09)	5.05 (± 0.98)	3.75 (± 1.72)	4.55 (± 1.5)

Notes:

[1] - Analysis on the patients completing the study per protocol

[2] - Analysis on the patients completing the study per protocol

[3] - Analysis on the patients completing the study per protocol

[4] - Analysis on the patients completing the study per protocol

Statistical analyses

Statistical analysis title	t-test
Comparison groups	Active Group v Control Group v Active Group v Control Group

Number of subjects included in analysis	134
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8532
upper limit	0.2532
Variability estimate	Standard deviation

Secondary: Analgesic outcome (WOMAC)

End point title	Analgesic outcome (WOMAC)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[5]	11[6]	56[7]	11[8]
Units: Scale				
arithmetic mean (standard deviation)				
Womac-Pain	10.15 (± 2.79)	11.18 (± 1.83)	7.23 (± 3.41)	9.27 (± 3.64)
Womac-Stiff	4.68 (± 1.41)	5.18 (± 1.17)	3.75 (± 1.64)	5.09 (± 1.51)
Womac-Phys	35.72 (± 9.03)	39.36 (± 7.19)	25.06 (± 11.75)	35.29 (± 11.67)
Womac-Glob	16.18 (± 3.79)	17.86 (± 2.42)	11.99 (± 4.99)	16.19 (± 4.73)

Notes:

[5] - Analysis on the patients completing the study per protocol

[6] - Analysis on the patients completing the study per protocol

[7] - Analysis on the patients completing the study per protocol

[8] - Analysis on the patients completing the study per protocol

Statistical analyses

No statistical analyses for this end point

Secondary: Analgesic outcome (BPI)

End point title	Analgesic outcome (BPI)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[9]	11[10]	56[11]	11[12]
Units: Scale				
arithmetic mean (standard deviation)				
BPI-Severity subscale	4.97 (± 1.37)	4.86 (± 1.17)	3.63 (± 1.81)	5.09 (± 1.63)
BPI-Interference	4.55 (± 1.82)	4.81 (± 1.19)	2.87 (± 2.02)	3.64 (± 1.69)
BPI-Effect	35.83 (± 21.25)	51.67 (± 20.41)	45.00 (± 24.49)	42.00 (± 19.24)

Notes:

[9] - Analysis on the patients completing the study per protocol

[10] - Analysis on the patients completing the study per protocol

[11] - Analysis on the patients completing the study per protocol

[12] - Analysis on the patients completing the study per protocol

Statistical analyses

No statistical analyses for this end point

Secondary: Analgesic outcome (WPS)

End point title	Analgesic outcome (WPS)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[13]	11[14]	56[15]	11[16]
Units: Scale				
arithmetic mean (standard deviation)	6.73 (± 1.16)	7.03 (± 1.31)	5.39 (± 2.03)	6.77 (± 1.59)

Notes:

[13] - Analysis on the patients completing the study per protocol

[14] - Analysis on the patients completing the study per protocol

[15] - Analysis on the patients completing the study per protocol

[16] - Analysis on the patients completing the study per protocol

Statistical analyses

No statistical analyses for this end point

Secondary: Analgesic outcome (LPS)

End point title	Analgesic outcome (LPS)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[17]	11[18]	56[19]	11[20]
Units: Scale				
arithmetic mean (standard deviation)	3.48 (± 1.75)	3.55 (± 1.41)	2.39 (± 1.80)	3.06 (± 1.55)

Notes:

[17] - Analysis on the patients completing the study per protocol

[18] - Analysis on the patients completing the study per protocol

[19] - Analysis on the patients completing the study per protocol

[20] - Analysis on the patients completing the study per protocol

Statistical analyses

No statistical analyses for this end point

Secondary: Analgesic outcome (IGAC and PGAC)

End point title	Analgesic outcome (IGAC and PGAC)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	11	56	11
Units: Scale				
arithmetic mean (standard deviation)				
PGAC	5.17 (± 1.60)	4.36 (± 1.80)	5.55 (± 2.32)	4.73 (± 1.90)
IGAC	5.23 (± 1.50)	5.09 (± 1.30)	5.28 (± 2.16)	4.82 (± 1.89)

Statistical analyses

No statistical analyses for this end point

Secondary: Personality characteristics outcomes

End point title	Personality characteristics outcomes

End point description:

End point type	Secondary

End point timeframe:

Change from baseline of during a 12-week treatment therapy period

End point values	Active Group	Control Group	Active Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	11	56	11
Units: Cronbach's alpha				
number (not applicable)	80.6	80.6	80.6	80.6

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
At each visit during treatment period	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Active Group
Reporting group description:	
Patients received T4P1010 treatment	
Reporting group title	Control Group
Reporting group description:	
Patients followed the control procedures, without T4P1010 treatment	

Serious adverse events	Active Group	Control Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 60 (1.67%)	1 / 12 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Skin and subcutaneous tissue disorders			
Erythema	Additional description: Patient reported a 5-days hospitalization due to pain in extremity and erythema, resolving 6 days later. The Investigator concluded that the 2 reported SAEs were not related to Study drug or to Protocol procedures and possibly due to previous gout		
subjects affected / exposed	1 / 60 (1.67%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Pain in extremity	Additional description: Patient reported a 5-days hospitalization due to pain in extremity and erythema, resolving 6 days later. The Investigator concluded that the 2 reported SAEs were not related to Study drug or to Protocol procedures and possibly due to previous gout		
subjects affected / exposed	1 / 60 (1.67%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Erysipelas	Additional description: Patient was hospitalized for 1 day following a cat bite on the left calf and diagnosed erysipelas. The SAE was therefore not related to Study Drug or to Study procedures, as supported by the Investigator conclusion.		

subjects affected / exposed	0 / 60 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Active Group	Control Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 60 (16.67%)	3 / 12 (25.00%)	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	3 / 60 (5.00%)	0 / 12 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 60 (3.33%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Infections and infestations			
Rhinitis			
subjects affected / exposed	5 / 60 (8.33%)	2 / 12 (16.67%)	
occurrences (all)	6	2	

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