Clinical trial results:
Treatment of the oral aphtose récidivante and idiopathique of the adult by probiotics
Double-blind randomized interventional study versus placebo

Summary

EudraCT number	2015-003944-38
Trial protocol	FR
Global end of trial date	24 December 2019

Results information

Result version number	v1 (current)
This version publication date	16 June 2022
First version publication date	16 June 2022
Summary attachment (see zip file)	end study (2015-003944-38_Rapport final.pdf) Publication (jdv_16199.pdf)

Trial information

Trial identification

Sponsor protocol code	15-PP-13

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	chu de nice
Sponsor organisation address	DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003
Public contact	Mme Caillon, CHU de Nice, 00 33492034589, caillon.c@chu-nice.fr
Scientific contact	Pr Thierry Passeron, CHU de Nice, 0492034589 33492036488, passeron.t@chu-nice.fr

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	27 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 September 2019
Global end of trial reached?	Yes
Global end of trial date	24 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effectiveness of a probiotic (Lactobacillus rhamnosus Lcr35®, Bacilor®) for the treatment of recurrent and idiopathic aphtous stomatitis compared to placebo after 3 months of treatment (M3)

Protection of trial subjects:

19 patients were randomized and signed consent

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 January 2018
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	France: 19
Worldwide total number of subjects	19
EEA total number of subjects	19

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)	16
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eligible participants were aged 18 or over, with history of RIAS (at least one new aphthous lesion each month during the past
6 months). ter central randomization, patients were allocated
to received oral suspension of 1.5 billion Lactobacillus rhamnosus
Lcr35 (Bacilor, Lyocentre laboratories) or placebo, four
times a day for 3 months

Period 1

Period 1 title	Inclusion Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Arm title	Bacilor or placebo

Arm description:

After central randomization, patients were allocated
to received oral suspension of 1.5 billion Lactobacillus rhamnosus
Lcr35 (Bacilor, Lyocentre laboratories) or placebo, four
times a day for 3 months.

Arm type	Experimental
Investigational medicinal product name	Bacilor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution and suspension for suspension for injection in pre-filled syringe
Routes of administration	Oral use

Dosage and administration details:

oral suspension of 1.5 billion Lactobacillus rhamnosus
Lcr35 (Bacilor, Lyocentre laboratories) or placebo, four
times a day for 3 months.

Number of subjects in period 1	Bacilor or placebo
Started	19
Completed	19

Baseline characteristics

End points

End points reporting groups

Reporting group title	Bacilor or placebo

Reporting group description:

After central randomization, patients were allocated to received oral suspension of 1.5 billion Lactobacillus rhamnosus Lcr35 (Bacilor, Lyocentre laboratories) or placebo, four times a day for 3 months.

Primary: The primary end point was the number of canker sores in the third month of treatment as compared to the month before the onset of the study.

End point title	The primary end point was the number of canker sores in the third month of treatment as compared to the month before the onset of the study.[1]

End point description:

End point type	Primary

End point timeframe:

In the third month of treatment

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: It's the difference between the patients with Bacilor and the patients with placebo.

End point values	Bacilor or placebo			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Number	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 6 times (V1, V2, V3 at 3 months, V4, V5, V6 at 6 months)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

Frequency threshold for reporting non-serious adverse events: 0 %

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 serious side effect was reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 January 2017	Modification de l'étiquette
11 January 2017	RGPD
10 January 2019	Diminution of number of patients : 20

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported