Clinical trial results:
Adjunctive effect of mouthrinse on treatment of periimplant mucositis using mechanical debridement: a randomized clinical trial

Summary

EudraCT number	2014-004825-42
Trial protocol	NL
Global end of trial date	09 February 2018

Results information

Result version number	v1 (current)
This version publication date	11 May 2020
First version publication date	11 May 2020
Summary attachment (see zip file)	Abstract (pubmed_abstract.txt)

Trial information

Trial identification

Sponsor protocol code	ACTA, Amsterdam

Additional study identifiers

ISRCTN number	ISRCTN52990000
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Effect of Delmopinol on treatment of inflammation : NL 5159

Notes:

Sponsors

Sponsor organisation name	ACTA
Sponsor organisation address	Gustav Mahlerlaan 3004, Amsterdam, Netherlands, 1081 LA
Public contact	Department of Oral Implantology, ACTA, 0031 205980297, info.implantologie@acta.nl
Scientific contact	Department of Oral Implantology, Academic Centre for Dentistry, 0031 205980297, j.philip@acta.nl

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	25 September 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study effect of delmopinol hydrochloride (DEL) in comparison with chlorhexidine digluconate (CHX) and a placebo (PLA) in addition to non-surgical mechanical debridement in patients with peri-implant mucositis.

Protection of trial subjects:

Standard treatment was provided to each participant.Patients could discontinue use of mouthrinse at any point of time.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 April 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	Netherlands: 89
Worldwide total number of subjects	89
EEA total number of subjects	89

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)	52
From 65 to 84 years	37
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The inclusion criteria of the study were: (a) individuals 18 years of age and older with at least one titanium dental implant, (b) single/three-unit fixed implant-supported restoration with bleeding on gentle probing (BOP) and/pus and (c) implant in function for at least 1 year, with no progressive radiographic bone loss.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	DELMOPINOL

Arm description:

Mechanical debridement combined with delmopinol mouthrinse

Arm type	Experimental
Investigational medicinal product name	delmopinol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Mouth rinsing 10 ml twice a day in addition to their regular oral hygiene practice

Arm title	CHLORHEXIDINE

Arm description:

Mechanical debridement combined with Chlorhexidine mouthrinse.

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

Dosage and administration details:

Mouth rinsing 0.2% CHX solution 10 ml twice a day in addition to their regular oral hygiene practice

Arm title	PLACEBO

Arm description:

Placebo mouthrinse

Arm type	Placebo

Investigational medicinal product name	Placebo mouthrinse
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Mouth rinsing Placebo mouthrinse 10 ml twice a day in addition to their regular oral hygiene practice

Number of subjects in period 1	DELMOPINOL	CHLORHEXIDINE	PLACEBO
Started	31	30	28
Completed	31	30	28

Baseline characteristics

End points

End points reporting groups	
Reporting group title	DELMOPINOL
Reporting group description:	
Mechanical debridement combined with delmopinol mouthrinse	
Reporting group title	CHLORHEXIDINE
Reporting group description:	
Mechanical debridement combined with Chlorhexidine mouthrinse.	
Reporting group title	PLACEBO
Reporting group description:	
Placebo mouthrinse	

Primary: Changes in mean mBI	
End point title	Changes in mean mBI
End point description:	
End point type	Primary
End point timeframe:	
Baseline, 1 and 3 months after treatment	

End point values	DELMOPINOL	CHLORHEXIDINE	PLACEBO	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	30	28	
Units: 1				
arithmetic mean (standard deviation)	1.00 (± 0.49)	1.03 (± 0.44)	1.08 (± 0.52)	

Statistical analyses

Statistical analysis title	Changes mean IBOP
Comparison groups	DELMOPINOL v CHLORHEXIDINE v PLACEBO
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
After baseline anytime and otherwise at 1 and 3 months after treatment.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

Frequency threshold for reporting non-serious adverse events: 2 %

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: Side effects reported were expected and there were no serious adverse events.

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32315444