Clinical trial results:
Comparison of the efficacy of treatment of chronic periodontitis with scaling and root-planning alone or in combination with azithromycin - a prospective, double blind, randomised clinical trial

Summary

EudraCT number	2015-004306-42
Trial protocol	SI
Global end of trial date	06 January 2020

Results information

Result version number	v1 (current)
This version publication date	06 March 2021
First version publication date	06 March 2021
Summary attachment (see zip file)	Article report (bmc.pdf) Demographic data (Table 1 Demographic and clinical characteristics of the treatment groups at baseline.docx) Healed sites (Table 2 Healed sites.docx) Risk factors (Table 3 Associations between risk factors.docx) 12 months outcomes (Table 4 12 months data.docx) Differences (Table 5 Differences in clinical characteristics between baseline and 12.docx) Raw data (Raw data.xlsx)

Trial information

Trial identification

Sponsor protocol code	2016-1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Stomatološka klinika UKC, Ljubljana
Sponsor organisation address	Hrvatski trg 6, Ljubljana, Slovenia, 1000
Public contact	CLinical Trials INformations, Stomatološka klinika UKC, Ljubljana, 00386 15224889, rok.gaspersic@mf.uni-lj.si
Scientific contact	CLinical Trials INformations, Stomatološka klinika UKC, Ljubljana, 00386 15224889, rok.gaspersic@mf.uni-lj.si

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	06 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 March 2018
Global end of trial reached?	Yes
Global end of trial date	06 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate if the number of diseased sites in patients with advanced chronic periodontitis will be different after adjunctive use of azithromycin in comprisson to mechanical debridement alone

Protection of trial subjects:

Regular check-up every 3 months.

Background therapy:

Scaling and root planing

Evidence for comparator: -

Actual start date of recruitment	01 February 2016
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	Slovenia: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Finished
Recruited between march 2016 and march 2018

Pre-assignment

Screening details:

732 screened
40 selected

Period 1

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

Blinding implementation details:

Identical appearance of active substance and placebo

Arms

Are arms mutually exclusive?	Yes
Arm title	Azithromycin

Arm description:

500 mg tablets

Arm type	Experimental
Investigational medicinal product name	Azibiot
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

500 mg every 24hrs 3 consecutive days

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

one tablet every 24 hrs 3 consecutive days

Number of subjects in period 1	Azithromycin	Placebo
Started	20	20
Completed	19	19
Not completed	1	1
tetraplegia due to accident	-	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Azithromycin
Reporting group description: 500 mg tablets	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Azithromycin	Placebo	Total
Number of subjects	20	20	40
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	44	45	
standard deviation	± 8	± 10	-
Gender categorical Units: Subjects			
Female	8	6	14
Male	12	14	26

End points

End points reporting groups	
Reporting group title	Azithromycin
Reporting group description: 500 mg tablets	
Reporting group title	Placebo
Reporting group description: -	

Primary: Diseased sites	
End point title	Diseased sites
End point description: Number of sites with PPD > 4 mm and BOP	
End point type	Primary
End point timeframe: 12 months	

End point values	Azithromycin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Number	4	6		

Statistical analyses

Statistical analysis title	Wilcoxon’s rank sum test
Statistical analysis description: Wilcoxon’s rank sum test	
Comparison groups	Azithromycin v Placebo
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Probing depth	
End point title	Probing depth
End point description:	
End point type	Secondary

End point timeframe:
12 months

End point values	Azithromycin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: mm				
median (inter-quartile range (Q1-Q3))				
12 months	2.7 (2.2 to 3.3)	2.7 (2.4 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical attachment loss

End point title	Clinical attachment loss

End point description:

End point type	Secondary

End point timeframe:
12 months

End point values	Azithromycin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: mm				
median (inter-quartile range (Q1-Q3))				
12 months	3.6 (2.9 to 4.8)	3.7 (2.7 to 4.2)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
6 months	
Adverse event reporting additional description:	
Nausea, headache	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	Azithromycin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Azithromycin	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Azithromycin	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	1 / 20 (5.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 20 (10.00%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	

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