Clinical trial results:
A Preliminary Randomised Controlled Trial using Standard Therapy Vs Mugard

Summary

EudraCT number	2010-019953-16
Trial protocol	GB
Global end of trial date	16 September 2013

Results information

Result version number	v1 (current)
This version publication date	31 August 2019
First version publication date	31 August 2019

Trial information

Trial identification

Sponsor protocol code	1009435

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Royal Devon and Exeter NHS Foundation Trust
Sponsor organisation address	Barrback Rd, Exeter, United Kingdom, EX2 5DW
Public contact	Clinical Trials Department, Royal Devon and Exeter NHS Foundation Trust, 01392 402215, clairebarber2@nhs.net
Scientific contact	Clinical Trials Department, Royal Devon and Exeter NHS Foundation Trust, 01392 402215, clairebarber2@nhs.net

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	16 September 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 September 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Does the use of Mugard in the management of patients with chemotherapy and/or radiotherapy-induced oral mucositis (severe intraoral ulceration), offer significant advantage in reducing the time of onset, duration or severity of intraoral lesions?

Protection of trial subjects:

Patient information sheets, patient questionnaires and weekly assessments with in between telephone contact if needed

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 August 2011
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	United Kingdom: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
QUESTIONNAIRES

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Mugard

Arm description:
Mugard is the new treatment undergoing investigation compared with benzydamine standard therapy

Arm type	standard intervention
Investigational medicinal product name	mugard
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Mouthwash
Routes of administration	Buccal use

Dosage and administration details:
SWISH AND SPIT AS DIRECTED ON PRESCRIPTION

Number of subjects in period 1	Mugard
Started	16
Completed	16

Baseline characteristics

End points

End points reporting groups

Reporting group title	Mugard
Reporting group description: Mugard is the new treatment undergoing investigation compared with benzydamine standard therapy	
Subject analysis set title	benzydamine difflam
Subject analysis set type	Intention-to-treat
Subject analysis set description: intention to treat	

Primary: • Delay onset, reduce severity and reduce duration of intra-oral lesions

End point title	• Delay onset, reduce severity and reduce duration of intra-oral lesions
End point description:	
End point type	Primary
End point timeframe: weekly assessment	

End point values	Mugard	benzydamine difflam		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	8	8		
Units: RTOG Scoring				
number (not applicable)	0	8		

Statistical analyses

Statistical analysis title	none done due to low numbers
Statistical analysis description: trial ended early due to withdrawal of investigative product	
Comparison groups	Mugard v benzydamine difflam
Number of subjects included in analysis	16
Analysis specification	Post-hoc
Analysis type	other[1]
P-value	≤ 0.01 [2]
Method	no analysis
Parameter estimate	no analysis

Notes:

[1] - not done

[2] - no analysis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: as per protocol	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Reporting groups	
Reporting group title	Serious adverse event
Reporting group description: -	

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: There were no NSAE within the trial

Serious adverse events	Serious adverse event		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Musculoskeletal and connective tissue disorders			
Hip disarticulation	Additional description: fell at home not related to investigation		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Serious adverse event		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

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