



Clinical trial results: Hibiscrub EN12791 Testing using current application and 2 new application methods

Summary

EudraCT number	2006-005470-41
Trial protocol	GB
Global end of trial date	12 January 2007

Results information

Result version number	v1 (current)
This version publication date	29 November 2019
First version publication date	29 November 2019

Trial information

Trial identification

Sponsor protocol code	CTR0028
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Regent Medical
Sponsor organisation address	Two Omega Drive, Irlam, United Kingdom, M44 5BJ
Public contact	Caroline Scott, Molnlycke Health Care, caroline.scott@molnlycke.com
Scientific contact	Suchismita Roy, Molnlycke Health Care, suchismita.roy@molnlycke.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	12 January 2007
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 January 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the study is to assess the suitability of a hand disinfectant product for surgical hand disinfection. The study will evaluate the hand disinfectant against a reference standard.

Primary Endpoints-

1. Immediate effect -
Reduction of the release of skin flora from the hands as assessed immediately after surgical hand disinfection.
2. 3-hour effect -
Reduction of the release of skin flora from the hands as assessed after wearing a surgical glove for 3 h following surgical hand disinfection

Protection of trial subjects:

The product used was a marketed product for use a topical hand wash

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 November 2006
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Aged 18-65, male or female

Able to communicate well with the investigator and to comply with the requirements of the entire study

Healthy skin on hands without cuts or abrasions

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Method 1

Arm description:

Application as per Manufacturers label instructions

Arm type	Active comparator
Investigational medicinal product name	PR1
Investigational medicinal product code	
Other name	Hibiscrub
Pharmaceutical forms	Cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

5ml applied rubbed for 1 min, rinse, 5ml application rubbed for 2 min, rinse, shake and dry

Arm title	Method 2
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Arm description:

New Application Method

Arm type	Active comparator
Investigational medicinal product name	PR1
Investigational medicinal product code	
Other name	Hibiscrub
Pharmaceutical forms	Cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

5ml application rubbed for 1 min, rinse

5ml application rubbed for 1 min, rinse

5ml application rubbed for 1 min, rinse, shake and dry

Arm title	Method 3
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Arm description:

New application method

Arm type	Active comparator
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Investigational medicinal product name	PR1
Investigational medicinal product code	
Other name	Hibiscrub
Pharmaceutical forms	Cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

Apply 5 mls of product and scrub for 1 minute, wash and rinse

Apply 5 mls of product and scrub for 2 minute, wash and rinse

Apply 5 mls of product and scrub for 2 minute, wash and rinse

Arm title	Reference
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Arm description:

As specified by the EN12791:2005 N-propanol with set instructions as the ideal efficacy results

Arm type	Reference
Investigational medicinal product name	PR2
Investigational medicinal product code	
Other name	N-Propanol
Pharmaceutical forms	Cutaneous liquid
Routes of administration	Cutaneous use

Dosage and administration details:

3 min rub

Number of subjects in period 1	Method 1	Method 2	Method 3
Started	20	20	20
Completed	20	20	20

Number of subjects in period 1	Reference
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Method 1
Reporting group description:	
Application as per Manufacturers label instructions	
Reporting group title	Method 2
Reporting group description:	
New Application Method	
Reporting group title	Method 3
Reporting group description:	
New application method	
Reporting group title	Reference
Reporting group description:	
As specified by the EN12791:2005 N-propanol with set instructions as the ideal efficacy results	

Reporting group values	Method 1	Method 2	Method 3
Number of subjects	20	20	20
Age categorical			
The actual ages of the participates was not recorded so using the inclusion criteria that they will be between 18-65			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Adult (18-65)	20	20	20
Gender categorical			
The data available for the gender of the trial participates is unavailable therefore data is token			
Units: Subjects			
Female	10	10	10
Male	10	10	10

Reporting group values	Reference	Total	
Number of subjects	20	20	
Age categorical			
The actual ages of the participates was not recorded so using the inclusion criteria that they will be between 18-65			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	

Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Adult (18-65)	20	20	
Gender categorical			
The data available for the gender of the trial participates is unavailable therefore data is token			
Units: Subjects			
Female	10	10	
Male	10	10	

End points

End points reporting groups

Reporting group title	Method 1
Reporting group description: Application as per Manufacturers label instructions	
Reporting group title	Method 2
Reporting group description: New Application Method	
Reporting group title	Method 3
Reporting group description: New application method	
Reporting group title	Reference
Reporting group description: As specified by the EN12791:2005 N-propanol with set instructions as the ideal efficacy results	

Primary: Comparison of bacterial efficacy of each arm to reference product - immediate

End point title	Comparison of bacterial efficacy of each arm to reference product - immediate
End point description:	
End point type	Primary
End point timeframe: Bacterial counts taken immediately after use and 3 hours after use and compared to counts down immediately after use	

End point values	Method 1	Method 2	Method 3	Reference
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	20	20
Units: Log reduction factor				
arithmetic mean (standard deviation)	1.18 (± 0.727)	1.25 (± 0.695)	1.58 (± 0.934)	3.01 (± 1.057)

Statistical analyses

Statistical analysis title	Reference V each method (Immediate)
Comparison groups	Method 2 v Method 1 v Method 3 v Reference
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 14
Method	Wilcoxon (Mann-Whitney)

Primary: Comparison of bacterial reduction factor for each application method and reference - 3 hour

End point title	Comparison of bacterial reduction factor for each application method and reference - 3 hour
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End point description:

End point type	Primary
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End point timeframe:

3 hours after application

End point values	Method 1	Method 2	Method 3	Reference
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	20	20
Units: Bacterial counts (log)				
log mean (standard deviation)	0.94 (\pm 1.065)	0.88 (\pm 0.906)	1.10 (\pm 0.799)	2.56 (\pm 1.470)

Statistical analyses

Statistical analysis title	Reference V each method (3 hour)
Comparison groups	Method 1 v Method 2 v Method 3 v Reference
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 24
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Subjects were monitored for the length of the trial - 4 weeks

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	9.1
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Reporting groups

Reporting group title	Overall Trial
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Reporting group description:

20 subjects enrolled and randomized to complete all 4 arms of the study over a 4 week period

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

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

Non-serious adverse events	Overall Trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		

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 was no non-serious AE reported due to the nature of the testing to a set standard and healthy volunteers taking part

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