Clinical trial results:
Treatment of MRSA throat carriage with mupirocin irrigation

Summary

EudraCT number	2014-005308-12
Trial protocol	DK
Global end of trial date	01 December 2020

Results information

Result version number	v1 (current)
This version publication date	19 December 2021
First version publication date	19 December 2021

Trial information

Trial identification

Sponsor protocol code	1111

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Region Sjælland, Slagelse Hospital
Sponsor organisation address	Ingemannsvej 18, Slagelse, Denmark, 4200
Public contact	Head of Research and Innovation, Region Sjælland, Operations, Research and Innovation, 45 58559404, insp@regionsjaelland.dk
Scientific contact	Head of Research and Innovation, Region Sjælland, Operations, Research and Innovation, 45 58559404, insp@regionsjaelland.dk

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	01 June 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 September 2020
Global end of trial reached?	Yes
Global end of trial date	01 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine if irrigation and wash of, respectively, the rhinopharynx and mouth with dissolved mupirocin is a feasible and potentially effi cious supplementary strategy against treatment resistant MRSA throat carriage.

Protection of trial subjects:

The patient was given all treatment instruction, including irrigation technique by a personal visit of the sponsor. Furthermore, the infection control nurse contacted the patient by phone in the beginning, in the middle and in the end of the treatment period, to ask how the treatment was going and to answer any questions the patient might have.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 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	Denmark: 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)	14
From 65 to 84 years	6

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was performed at the outpatient MRSA sections of three Departments of Clinical Microbiology (Slagelse Hospital, Herlev Hospital, and Hvidovre Hospital) covering all outpatients in two neighboring regions of East-Denmark; Region Zealand and The Capital Region. Approximately 2,7 million citizens live in these two regions.

Pre-assignment

Screening details:

The design and study group was an open, non-blinded, trial of a cohort of 20 patients. None of the patients were hospitalized and all were living in their own home. All patients received the same treatment.
Inclusion of patients was done by medical assessment in the two regions in the participating MRSA units and microbiological departments.

Period 1

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

Blinding implementation details:

No blinding

Arms

Arm title	End-point data

Arm description: -

Arm type	All subjects
Investigational medicinal product name	mupirocin ointment (22 g 2% ointment per liter of isotonic sterile saline solution) in a 37 degrees Celsius solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal/oromucosal spray, solution, Gargle/mouthwash
Routes of administration	Other use

Dosage and administration details:

For each patient, mupirocin ointment 2% (GlaxoSmithKline) was dispensed into 28 small bottles for treatments twice a day in 14 days, each bottle with an amount of ointment equivalent to a treatment. The ointment from a bottle was by the patient mixed with 37o C 120 ml of a sterile fluid of saline 0.9% prior to each treatment to achieve the right amount of mupirocin solution (22 g 2% ointment per liter of isotonic sterile saline solution) [9]. The temperature of the solution was controlled by a thermometer that each patient received prior to the treatment.
The patient performed rhinopharynx irrigation and mouth gurgling with a mupirocin solution every morning and evening for 14 days. Rhinopharynx irrigation was performed using a Neti pot (Rhinohorn, Yogaprosess AS, Norway) through each nostril with 50 mL mupirocin solution twice daily, and also mouth gurgle with 20 ml mupirocin solution in 20 seconds was done twice daily.

Number of subjects in period 1	End-point data
Started	20
Completed	18
Not completed	2
Protocol deviation	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	20	20	
Age categorical 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)	14	14	
From 65-84 years	6	6	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	12	12	
Male	8	8	

End points

End points reporting groups

Reporting group title	End-point data

Reporting group description: -

Primary: Number of trail subjects with negativ MRSA podning at 6 months

End point title	Number of trail subjects with negativ MRSA podning at 6 months[1]

End point description:

Before start of treatment, as well as six months after end of treatment, swabs were collected from nose, throat and perineum (the latter only one time before start of treatment) by the patients general practitioner as recommended in "Guidance on preventing the spread of MRSA" by the Danish Health Authority [2]. All samples were collected using ESwab (COPAN Diagnostics, Murrieta, California).

End point type	Primary

End point timeframe:

6 months after intervention

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: Please see the attachment. Result

End point values	End-point data			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Number	7			

Attachments (see zip file)	Result/Table 1.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Number of trail subjects with negativ MRSA podning at 1 month

End point title	Number of trail subjects with negativ MRSA podning at 1 month

End point description:

Before start of treatment and after one month after end of treatment, swabs were collected from nose, throat and perineum (the latter only one time before start of treatment) by the patients general practitioner as recommended in "Guidance on preventing the spread of MRSA" by the Danish Health Authority [2]. All samples were collected using ESwab (COPAN Diagnostics, Murrieta, California).

End point type	Secondary

End point timeframe:

Number of subjects with a negative MRSA podning one month after intervention

End point values	End-point data			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Number	15			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From informed consent to end of intervention	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	0
Reporting groups	
Reporting group title	All trail

Reporting group description: -

Serious adverse events	All trail		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All trail		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 18 (38.89%)		
Nervous system disorders			
headache			
subjects affected / exposed	3 / 18 (16.67%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Fluid running from the nose			
subjects affected / exposed	3 / 18 (16.67%)		
occurrences (all)	2		
Few episodes with sneezing			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Metabolism and nutrition disorders			

Bad taste in the mouth subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2		

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/34699965