



Clinical trial results: Reduction of postoperative wound infections by antiseptica Summary

EudraCT number	2014-001551-22
Trial protocol	DE
Global end of trial date	26 June 2018

Results information

Result version number	v1 (current)
This version publication date	09 February 2020
First version publication date	09 February 2020
Summary attachment (see zip file)	Summary_RECIPe (Summary.pdf)

Trial information

Trial identification

Sponsor protocol code	RECIPe2014
-----------------------	------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charite Universitaetsmedizin berlin
Sponsor organisation address	Hindenburgdamm 30, Berlin, Germany, 12200
Public contact	study coordinator, Charité Universitätsmedizin, 0049 03084452948, marja.leonhardt@charite.de
Scientific contact	study coordinator, Charité Universitätsmedizin, 0049 03084452948, marja.leonhardt@charite.de

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	10 April 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 June 2018
Global end of trial reached?	Yes
Global end of trial date	26 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Randomised controlled trial testing if the antiseptic subcutaneous applied solution SERASEPT is capable of reducing postoperative wound infections compared to NaCl-Solution in visceral surgery

Protection of trial subjects:

All patients were interviewed 30 days postoperatively and asked for pain and satisfaction with the cosmetic result. In case of questions or need for clinical examination, all patients were advised to come to our emergency department.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2014
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	Germany: 456
Worldwide total number of subjects	456
EEA total number of subjects	456

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)	270
From 65 to 84 years	182
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Patients were enrolled by one of the surgeons involved in the trial either on surgical ward or in preoperative outpatient clinic at the Charite hospital Campus Benjamin Franklin berlin between 02/15 and 05/18.

Pre-assignment

Screening details:

Patients > 18, capable to give informed consent and undergoing elective open or laparoscopic-assisted gastrointestinal surgery with mini-laparotomy were eligible to participate. Patients with emergency operations, laparoscopic surgery, surgery of the abdominal wall, vascular surgery or allergy to one of the irrigation solutions were excluded.

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

Blinding implementation details:

only patients were blinded. there was no blinding of the operating surgeon as the application time differed between saline and polyhexanide.

Arms

Are arms mutually exclusive?	Yes
Arm title	Control group

Arm description:

subcutaneous
irrigation with 250mL 0.9% saline

Arm type	Treatment as usual
Investigational medicinal product name	Na CL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

subcutaneous irrigation with 250mL 0.9% saline

Arm title	Experimental group
------------------	--------------------

Arm description:

250mL antiseptic 0.04% polyhexanide solution

Arm type	Experimental
Investigational medicinal product name	Serasept 2, Serag Wiessner
Investigational medicinal product code	57862.00.00
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

After the closure of fascia, subcutaneous
irrigation with 250mL antiseptic 0.04% polyhexanide solution

Number of subjects in period 1[1]	Control group	Experimental group
Started	208	201
Completed	208	201

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Control group: 228 assigned wound irrigation with 0.9% saline, but due to 3x consent, withdrawn, 5x no wound irrigation: 3x laparoscopic surgery, 1x no skin closure, 1x transanal surgery, 10x wrong irrigation, 2x refusal of surgery only 208 had wound irrigation with 0.9% saline.

Experimental gruoup: 228 assigned wound irrigation with 0.04% polyhexanide, but due to 8x consent withdrawn, 1x no wound irrigation: ostomy in incision, 16x wrong irrigation, 1x double randomization 1x surgery canceled

Baseline characteristics

End points

End points reporting groups

Reporting group title	Control group
Reporting group description: subcutaneous irrigation with 250mL 0.9% saline	
Reporting group title	Experimental group
Reporting group description: 250mL antiseptic 0.04% polyhexanide solution	

Primary: incidence of any SSI

End point title	incidence of any SSI
End point description:	
End point type	Primary
End point timeframe: 30 days after surgery	

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	202	191		
Units: number of patients	202	191		

Statistical analyses

Statistical analysis title	cross tabulation and the chi-squared test.
Statistical analysis description: The biometric outcome assessor was blinded to the allocation for the analysis of the trial. The primary hypothesis was analyzed with cross tabulation and the chi-squared test. We analyzed the primary endpoint—the rate of SSI within 30 days postoperatively—with the per protocol population and confirmed the results with the intention to treat population. For categorical outcomes such as our secondary parameters, statistical group comparisons were performed using chi-square test. Because of	
Comparison groups	Control group v Experimental group
Number of subjects included in analysis	393
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Chi-squared

Secondary: Rate of colonization of the abdominal wall with bacteria in the intraoperative swab after irrigation.

End point title	Rate of colonization of the abdominal wall with bacteria in the intraoperative swab after irrigation.
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

30 days after surgery

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	202	191		
Units: Type and number of bacterial species	202	191		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of hospital stay in days

End point title	Length of hospital stay in days
-----------------	---------------------------------

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

Up to one month after recruitment

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	202	191		
Units: days	202	191		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From recruitment of the first patient to the end of follow-up of the last enrolled patient (02/15-06/18)

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	CTCAE
-----------------	-------

Dictionary version	5.0
--------------------	-----

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

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: We have not recorded any non-serious events in the trial

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/31599810>