Clinical trial results:
SOAP Antibiotic prophylaxis trial

Systemic versus combined systemic and Oral Antibiotic Prophylaxis in elective colorectal surgery

Summary

EudraCT number	2015-005614-30
Trial protocol	HU
Global end of trial date	25 July 2018

Results information

Result version number	v1 (current)
This version publication date	26 February 2020
First version publication date	26 February 2020

Trial information

Trial identification

Sponsor protocol code	SOAP2016

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Uzsoki Utcai Kórház, Surgical and Oncosurgical Ward
Sponsor organisation address	Róna str, Budapest, Hungary,
Public contact	Surgical and Oncosurgical Ward, Uzsoki Utcai Kórház, 36 146737003794, papgez@gmail.com
Scientific contact	Surgical and Oncosurgical Ward, Uzsoki Utcai Kórház, 36 146737003794, papgez@gmail.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	09 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 June 2018
Global end of trial reached?	Yes
Global end of trial date	25 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This trial is designed to assess the benefit of oraly administred antibiotic prophylaxis beside bowelprep and venous antibiotic prophylaxis versus bowelprep and systemic antibiotic prophylaxis alone. The scope are postoperative and infective complications.

Protection of trial subjects:

1. The current revision of the Declaration of Helsinki is the accepted as a basis for this trial ethics, and was fully followed and respected.
2. The trial has permission of National Institute of Pharmacy and Nutrition Health and of Medical Research Council of Hungary.
3. The principles of informed consent in the current revisions of the Declaration of Helsinki (Appendix 1) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2) was implemented.
4. The investigators established secure safeguards of confidentiality of research data as described in the current revision of the International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 November 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Hungary: 600
Worldwide total number of subjects	600
EEA total number of subjects	600

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)	300
From 65 to 84 years	270
85 years and over	30

Subject disposition

Recruitment

Recruitment details:

Elective colorectal resections with planned anastomosis

Pre-assignment

Screening details:

Age over 18
No abdominal sepsis 6 month prior assignment
No antibiotic therapy 2 weeks prior assignment
Pregnancy
Lactation
Chronic immune supprimed
Steroid use

Period 1

Period 1 title	overall period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	OABP+

Arm description:

Patients recieved TID metranidasol 500mg and TID neonycine sulphat 1000mg

Arm type	Experimental
Investigational medicinal product name	metronidasol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

TID metranidasol 500mg

Investigational medicinal product name	neomycine sulphat
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

TID neomycine sulphat 1000mg

Arm title	OABP-

Arm description:

No oral antibiotic prophylaxis

Arm type	No intervention

No investigational medicinal product assigned in this arm

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: 2 arms, randomised trial.
Assessor was blind.

Number of subjects in period 1	OABP+	OABP-
Started	298	302
Completed	274	302
Not completed	24	0
Adverse event, non-fatal	7	-
Protocol deviation	17	-

Baseline characteristics

Reporting groups	
Reporting group title	overall period

Reporting group description: -

Reporting group values	overall period	Total	
Number of subjects	600	600	
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			
median	66.3		
standard deviation	± 12.2	-	
Gender categorical Units: Subjects			
Female	280	280	
Male	320	320	

End points

End points reporting groups	
Reporting group title	OABP+
Reporting group description:	
Patients recieved TID metranidasol 500mg and TID neonycine sulphat 1000mg	
Reporting group title	OABP-
Reporting group description:	
No oral antibiotic prophylaxis	

Primary: SSI (surgical site infection)	
End point title	SSI (surgical site infection)
End point description:	
End point type	Primary
End point timeframe:	
Within 30 days after recieving oral antibiotic prophylaxis	

End point values	OABP+	OABP-		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	276		
Units: number of patients	8	27		

Statistical analyses

Statistical analysis title	z test
Comparison groups	OABP- v OABP+
Number of subjects included in analysis	529
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	Regression, Linear

Primary: POI (postoperative ileus)	
End point title	POI (postoperative ileus)
End point description:	
End point type	Primary
End point timeframe:	
30 days within recieving the oral antibiotic prophylaxis	

End point values	OABP+	OABP-		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	276		
Units: number of patients	16	16		

Statistical analyses

Statistical analysis title	z test
Comparison groups	OABP+ v OABP-
Number of subjects included in analysis	529
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Regression, Linear

Secondary: AI (Anastomos insufficiency)

End point title	AI (Anastomos insufficiency)

End point description:

End point type	Secondary

End point timeframe:

30 days within recieving the oral antibiotic prophylaxis

End point values	OABP+	OABP-		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	276		
Units: Number of patients	4	13		

Statistical analyses

No statistical analyses for this end point

Secondary: 30day readmission

End point title	30day readmission

End point description:

End point type	Secondary

End point timeframe:
30 days within recieving the oral antibiotic prophylaxis

End point values	OABP+	OABP-		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	276		
Units: number of patients	12	10		

Statistical analyses

No statistical analyses for this end point

Secondary: 30 day mortality

End point title	30 day mortality

End point description:

End point type	Secondary

End point timeframe:
30 days within recieving the oral antibiotic prophylaxis

End point values	OABP+	OABP-		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	276		
Units: number of patients	3	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days within recieving the oral antibiotic prophylaxis	
Adverse event reporting additional description: daily questionnaire	
Assessment type	Systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	1

Reporting groups	
Reporting group title	OABP+

Reporting group description: -

Serious adverse events	OABP+		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 274 (0.00%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events			

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

Non-serious adverse events	OABP+		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 274 (10.58%)		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	29 / 274 (10.58%)		
occurrences (all)	29		

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