



## Clinical trial results:

### Optimizing Colon Capsule Endoscopy in follow up program on patients with colorectal polyps assessing three booster procedures for motility enhancement

#### Summary

EudraCT number	2016-002237-30
Trial protocol	DK
Global end of trial date	01 November 2017

#### Results information

Result version number	v1 (current)
This version publication date	27 January 2021
First version publication date	27 January 2021
Summary attachment (see zip file)	Article (10-1055-a-0732-494.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	CAREforCOLONbooster
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##### Additional study identifiers

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

Notes:

##### Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	Baagøes Alle, Svendborg, Denmark,
Public contact	Research Unit, Department of Surgery, OUH Odense University Hospital, Svendborg Sygehus, akd@rsyd.dk
Scientific contact	Research Unit, Department of Surgery, OUH Odense University Hospital, Svendborg Sygehus, akd@rsyd.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	07 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2017
Global end of trial reached?	Yes
Global end of trial date	01 November 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The objective of the study is to establish which booster procedure best facilitates timely excretion of CCE.

Protection of trial subjects:

Exclusion criteria were previous bowel surgery except appendectomy, renal insufficiency, pacemaker, pregnancy, breastfeeding, inflammatory bowel disease or allergies towards active substances administered in the trial. All participants who commenced bowel preparation were included in the analyses as intention to treat. All participants signed informed written consent.

Background therapy:

All participants received a bowel preparation consisting of magnesium tablets, 2-L split-dose PEG solution (Moviprep, Norgine, Denmark) and were kept on a diet of watery fluids.

Evidence for comparator:

We designed a three arm randomized trial to assess three different booster regimen's effect on excretion. Moviprep, Eziclen and moviprep with gastrografin has previously been reported as well tolerated, low risk and effective.

Actual start date of recruitment	01 February 2017
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: 180
Worldwide total number of subjects	180
EEA total number of subjects	180

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)	109
From 65 to 84 years	71
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Patients scheduled for follow-up colonoscopy at Odense University Hospital and Hospital of Southwest Jutland between February 1st, 2017 and November 1st, 2017 were screened. Inclusion criteria were follow-up due to previous neoplastic findings or familial history of colorectal cancer and age 18 to 70 years. Exclusion criteria were previous bowe

### Pre-assignment

Screening details:

A total of 1707 patients were screened for eligibility and 517 invitations were sent. We included 180 eligible consecutive patients that responded and fulfilled the criteria. We included 140 (78%) participants at center one, and 40 (22%) participants at center two

### 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	Data analyst <sup>[1]</sup>

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Moviprep

Arm description:

Moviprep booster

Arm type	Active comparator
Investigational medicinal product name	Moviprep
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in sachet
Routes of administration	Oral use

Dosage and administration details:

Booster regimen

Signal 1

(Capsule reached the small bowel)

0.75 L Moviprep® solution

0.75 L water

Signal 2

(3 hours after signal 1)

0.25 L Moviprep® solution

0.25 L water

Signal 3

(2 hours after signal 2)

10 mg Rectal Bisacodyl

1 hour after Signal 3: No dietary restrictions

<b>Arm title</b>	Eziclen
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Arm description:	
Eziclen Booster	
Arm type	Experimental
Investigational medicinal product name	Eziclen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Booster regimen

Signal 1

(Capsule reached the small bowel)

0.25 L Eziclen® solution

0.75 L water

Signal 2

(3 hours after signal 1)

0.25 L Eziclen® solution

0.75 L water

Signal 3

(2 hours after signal 2) Group A Group B Group C

10 mg Rectal Bisacodyl

1 hour after Signal 3: No dietary restrictions

<b>Arm title</b>	Moviprep + Gastrografin
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Arm description:

Moviprep + Gastrografin booster

Arm type	Experimental
Investigational medicinal product name	Moviprep
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in sachet
Routes of administration	Oral use

Dosage and administration details:

Booster regimen

Signal 1

(Capsule reached the small bowel)

0.75 L Moviprep® solution

0.75 L water

Signal 2

(3 hours after signal 1)

0.25 L Moviprep® solution

0.25 L water

Signal 3

(2 hours after signal 2)

10 mg Rectal Bisacodyl

1 hour after Signal 3: No dietary restrictions

Investigational medicinal product name	Gastrografin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Booster regimen

Signal 1

(Capsule reached the small bowel)

50 mL Gastrografin®

Signal 2

(3 hours after signal 1)

25 mL Gastrografin®

Signal 3

(2 hours after signal 2)

10 mg Rectal Bisacodyl

1 hour after Signal 3: No dietary restrictions

Notes:

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

Justification: Included individuals and nurses delivering the investigations were not blinded. But arm randomization was blinded to assessors, investigator and data analyst.

<b>Number of subjects in period 1</b>	Moviprep	Eziclen	Moviprep + Gastrografin
Started	60	60	60
Completed	54	57	57
Not completed	6	3	3
Adverse event, non-fatal	6	3	3

## Baseline characteristics

### Reporting groups

Reporting group title	Moviprep
Reporting group description:	
Moviprep booster	
Reporting group title	Eziclen
Reporting group description:	
Eziclen Booster	
Reporting group title	Moviprep + Gastrografin
Reporting group description:	
Moviprep + Gastrografin booster	

Reporting group values	Moviprep	Eziclen	Moviprep + Gastrografin
Number of subjects	60	60	60
Age categorical			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Units: years			
median	59	58	58
full range (min-max)	34 to 70	38 to 70	32 to 70
Gender categorical			
Units: Subjects			
Female	32	25	30
Male	28	35	30

Reporting group values	Total		
Number of subjects	180		
Age categorical			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years)	0 0 0 0 0 0 0		

From 65-84 years	0		
85 years and over	0		

Age continuous			
Units: years			
median			
full range (min-max)	-		
Gender categorical			
Units: Subjects			
Female	87		
Male	93		

## End points

### End points reporting groups

Reporting group title	Moviprep
Reporting group description:	
Moviprep booster	
Reporting group title	Eziclen
Reporting group description:	
Eziclen Booster	
Reporting group title	Moviprep + Gastrografin
Reporting group description:	
Moviprep + Gastrografin booster	

### Primary: Capsule excretion

End point title	Capsule excretion
End point description:	
Timely anal excretion of the capsule while recording	
End point type	Primary
End point timeframe:	
At investigation	

End point values	Moviprep	Eziclen	Moviprep + Gastrografin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	60	60	
Units: Individuals				
Excreted	42	44	41	
Not excreted	18	16	19	

### Statistical analyses

Statistical analysis title	confidence interval
Comparison groups	Moviprep v Eziclen v Moviprep + Gastrografin
Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	other <sup>[1]</sup>
P-value	> 0.05
Method	t-test, 2-sided

Notes:

[1] - 95% Confidence intervals was reported for each group

### Secondary: Adequate bowel preparation

End point title	Adequate bowel preparation
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End point description:

Bowel cleanliness was graded according to the validated Leighton-Rex scale from 1-4 (1: Poor, 2: Fair, 3: Good, 4: Excellent)[30]. Bowel cleansing grade 2-4 was regarded as adequate for clinical purposes. An investigation with no images of the colon due to slow transit was regarded as bowel cleansing grade 1. A video with images of the anal verge was regarded as excreted.

End point type	Secondary
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End point timeframe:

At video investigation

End point values	Moviprep	Eziclen	Moviprep + Gastrografin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	60	60	
Units: Individuals				
Adequate	47	57	53	
Inadequate	13	3	7	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Complete examination

End point title	Complete examination
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End point description:

In order to obtain a complete examination the individual should have a timely capsule excretion and an adequate bowel preparation

End point type	Secondary
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End point timeframe:

Composite endpoint

End point values	Moviprep	Eziclen	Moviprep + Gastrografin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	60	60	
Units: Individuals				
Complete	39	43	37	
Incomplete	21	17	23	

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Trial start and until 2 days after capsule excretion.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	2
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### Reporting groups

Reporting group title	Moviprep
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Reporting group description:

Moviprep booster

Reporting group title	Eziclen
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Reporting group description:

Eziclen Booster

Reporting group title	Moviprep + Gastrografin
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Reporting group description:

Moviprep + Gastrografin booster

Serious adverse events	Moviprep	Eziclen	Moviprep + Gastrografin
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Moviprep	Eziclen	Moviprep + Gastrografin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 60 (10.00%)	3 / 60 (5.00%)	3 / 60 (5.00%)
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	6 / 60 (10.00%)	3 / 60 (5.00%)	3 / 60 (5.00%)
occurrences (all)	6	3	3

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported