



Clinical trial results:

Adherence of a 1.600 mg single tablet 5-ASA treatment of Ulcerative colitis (EASI-trial)

Summary

EudraCT number	2019-002070-31
Trial protocol	DK
Global end of trial date	07 January 2025

Results information

Result version number	v1 (current)
This version publication date	13 March 2026
First version publication date	13 March 2026
Summary attachment (see zip file)	Summary from medical journal (APT-62-877.pdf)

Trial information

Trial identification

Sponsor protocol code	1337-EASI-trial
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Copenhagen University Hospital Hvidovre
Sponsor organisation address	Kettegård alle 30, Hvidovre, Denmark,
Public contact	The Gastro Unit, medical section, Copenhagen University Hospital Hvidovre, gastroenhed.hvidovrehospital@regionh.dk
Scientific contact	The Gastro Unit, medical section, Copenhagen University Hospital Hvidovre, gastroenhed.hvidovrehospital@regionh.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	27 May 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 January 2025
Global end of trial reached?	Yes
Global end of trial date	07 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether a simplified treatment regimen for Mesalazine (5- ASA) (1600 mg as one tablet per day [intervention]) improves adherence compared to conventional therapy.

Protection of trial subjects:

No specific were put in place

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2019
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	Denmark: 178
Worldwide total number of subjects	178
EEA total number of subjects	178

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)	165
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was an open-label randomised controlled phase IV trial including 190 patients with ulcerative colitis in remission. Patients were recruited from November 2019 to March 2024 through the outpatient clinic at the Gastrounit, Medical Division at Copenhagen University Hospital—Amager and Hvidovre.

Pre-assignment

Screening details:

Patients had to have an age between 18 and 70 years, inclusive, at the time of inclusion. Additionally, patients had to be in stable remission on 5-ASA (defined as partial Mayo score ≤ 1) for at least 2 months and have endoscopic remission (Mayo Clinic Endoscopic Score ≤ 1) if inclusion endoscopy was performed. Patients were excluded from the

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	1600 mg ASACOL arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ASACOL 1600 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Gastroenteral use

Dosage and administration details:

1 tablet of 1600 mg ASACOL once daily

Arm title	2400 mg ARM
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	2400 mg ASACOL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Gastroenteral use

Dosage and administration details:

3, 800 mg ASACOL tablet once daily

Number of subjects in period 1	1600 mg ASACOL arm	2400 mg ARM
Started	89	89
Completed	79	79
Not completed	10	10
Lack of time	3	2
Consent withdrawn by subject	-	3
Adverse event, non-fatal	2	-
Lack of efficacy	5	5

Baseline characteristics

End points

End points reporting groups

Reporting group title	1600 mg ASACOL arm
Reporting group description:	-
Reporting group title	2400 mg ARM
Reporting group description:	-

Primary: Medical adherence

End point title	Medical adherence
End point description:	medical adherence as measured by MARS-5 score and through drug accountability log
End point type	Primary
End point timeframe:	1 year

End point values	1600 mg ASACOL arm	2400 mg ARM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	89		
Units: s				
number (not applicable)	82	78		

Statistical analyses

Statistical analysis title	Adherence $\geq 80\%$
Comparison groups	1600 mg ASACOL arm v 2400 mg ARM
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32 ^[1]
Method	Chi-squared

Notes:

[1] - non-significant

Adverse events

Adverse events information

Timeframe for reporting adverse events:

November 2019 to January 2025

Adverse event reporting additional description:

None related to the IMP

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Reporting groups

Reporting group title	1600 mg arm
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Reporting group description: -

Reporting group title	2400 mg arm
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Reporting group description: -

Serious adverse events	1600 mg arm	2400 mg arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 89 (14.61%)	5 / 89 (5.62%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck discomfort			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Lymphangitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Emergency cesarean section			

subjects affected / exposed	2 / 89 (2.25%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AV nodal tachycardia			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NSTEMI			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Laryngitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicectomy			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Erysipelas			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			

subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Meningitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypokalemia			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	1600 mg arm	2400 mg arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 89 (20.22%)	13 / 89 (14.61%)	
Injury, poisoning and procedural complications			
Subluxation shoulder			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences (all)	1	0	
Broken bones			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences (all)	0	1	
Tendon injury			
subjects affected / exposed	0 / 89 (0.00%)	1 / 89 (1.12%)	
occurrences (all)	0	1	
Cardiac disorders			
Heart pounding			
subjects affected / exposed	1 / 89 (1.12%)	0 / 89 (0.00%)	
occurrences (all)	1	0	
Heart rate high			

subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Chest ache subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Palpitations subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Nervous system disorders Amnesia subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Facial paraesthesia subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Migraine subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Tension headache (excl migraine) subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Ear and labyrinth disorders Otitis media subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Left otitis externa subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 89 (2.25%) 2	0 / 89 (0.00%) 0	
Nausea and vomiting symptoms subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Fissure in ano			

subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Reproductive system and breast disorders			
Menopausal menorrhagia subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Polyp of cervix subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Hepatobiliary disorders			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Primary sclerosing cholangitis subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Gallstone attack subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Skin and subcutaneous tissue disorders			
Haematoma subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Papule subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Erythema subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Renal and urinary disorders			
Recurrent UTI			

subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 2	
Incontinence of urine subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Kidney stones subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Musculoskeletal and connective tissue disorders Carpal tunnel syndrome subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	
Polyarthritis subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	1 / 89 (1.12%) 1	
Metabolism and nutrition disorders Iron deficiency subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1	0 / 89 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 October 2022	Redefinition of inclusion criteria allowing omission of Sigmoidoscopy

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported