Clinical trial results:
Evaluating the vulnerability of traditional and transposition FAMM flaps using microdialysis

Summary

EudraCT number	2022-003858-31
Trial protocol	DK
Global end of trial date	27 January 2025

Results information

Result version number	v1
This version publication date	18 May 2026
First version publication date	18 May 2026

Trial information

Trial identification

Sponsor protocol code	300319

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 99, Aarhus N, Denmark, 8200
Public contact	Pelle Hanberg, Aarhus University Hospital, pellehanberg@clin.au.dk
Scientific contact	Pelle Hanberg, Aarhus University Hospital, pellehanberg@clin.au.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 January 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 January 2025
Global end of trial reached?	Yes
Global end of trial date	27 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives is: 1) To compare ischemic metabolites between conventional and transposition FAMM Flap. 2) To compare inflammation proteins between conventional and transposition FAMM Flap. 3) To compare concentrations of metronidazole and cefuroxime between conventional and transposition FAMM Flap. 4) To compare concentrations of metronidazole following per oral and intravenous use. 5) To compare concentrations of cefuroxime concentrations bolus and continuous infusion.

Protection of trial subjects:

The trial was conducted in accordance with the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki.
All participants received both oral and written information about the study and were given adequate time to consider participation before providing written informed consent. Participation in the study was entirely voluntary, and participants were free to withdraw from the study at any time without any consequences for their further treatment.
The study protocol was approved by the relevant Ethics Committee and the national competent authority prior to initiation of the trial.
The interventions used in the study were based on standard clinical practice. The investigational procedures, including placement of microdialysis catheters, were considered to involve minimal additional risk. Potential risks and side effects, including those related to antibiotic treatment, were clearly described to participants.
All adverse events were monitored and managed according to standard clinical practice.
Personal data were handled confidentially and in compliance with applicable data protection regulations. Data were pseudonymised to protect participant identity.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2023
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: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	12
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited consecutively from patients scheduled for surgery for oral cavity cancer at Aarhus University Hospital. Eligible patients were identified during preoperative assessment, informed orally and in writing, and included after providing written informed consent.

Pre-assignment

Screening details:

Patients were screened during preoperative assessment for eligibility based on inclusion and exclusion criteria, including planned reconstruction with a FAMM flap, age ≥18 years, and absence of allergy to cefuroxime or metronidazole.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard treatment

Arm description:

cefuroxime as bolus and metronidazole iv

Arm type	Experimental
Investigational medicinal product name	Cefuroxime
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

1500 mg as bolus dose over 5 min

Investigational medicinal product name	Metronidazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

500 mg as bolus dose over 5 min

Arm title	New treatment

Arm description:

Cefuroxime continuous use and metronidazole po

Arm type	Experimental
Investigational medicinal product name	Cefuroxime
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for suspension for injection
Routes of administration	Intravenous drip use

Dosage and administration details:

1500 mg given over 8 hours

Investigational medicinal product name	Metronidazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

500 mg over 5 min

Number of subjects in period 1	Standard treatment	New treatment
Started	15	9
Completed	15	9

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	24	24	
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)	12	12	
From 65-84 years	12	12	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	8	8	
Male	16	16	

End points

End points reporting groups	
Reporting group title	Standard treatment
Reporting group description: cefuroxime as bolus and metronidazole iv	
Reporting group title	New treatment
Reporting group description: Cefuroxime continuous use and metronidazole po	

Primary: T>MIC	
End point title	T>MIC
End point description:	
End point type	Primary
End point timeframe: 0-8 h	

End point values	Standard treatment	New treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	9		
Units: min	15	9		

Attachments (see zip file)	Metronidazole transposition FAMM flap/Skærmbillede 2026-05- Cefuroxime conventional FAMM flap/Skærmbillede 2026-05-02 Cefuroxime transposition FAMM flap/Skærmbillede 2026-05-02 Metronidazole conventional FAMM flap/Skærmbillede 2026-05-

Statistical analyses

Statistical analysis title	non-compartmental analysis in STATA
Comparison groups	New treatment v Standard treatment
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	ANOVA

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	97.2

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from: 16/2-2023 To 27/1-2025	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	0

Reporting groups	
Reporting group title	standerd treatment
Reporting group description: -	
Reporting group title	new treatment
Reporting group description: -	

Serious adverse events	standerd treatment	new treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	standerd treatment	new treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	

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: No adverse events were found for this study

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/42066992

http://www.ncbi.nlm.nih.gov/pubmed/41790509

http://www.ncbi.nlm.nih.gov/pubmed/41407330