



Clinical trial results: Cytotoxicity of Yellow Fever specific CD8 T cells Following YF-17D Vaccination

Summary

EudraCT number	2019-001731-31
Trial protocol	DK
Global end of trial date	01 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	YFV_001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04083430
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 45, Aarhus N, Denmark, 8200
Public contact	Jesper D. Gunst, Aarhus University Hospital, jesdam@rm.dk
Scientific contact	Jesper D. Gunst, Aarhus University Hospital, jesdam@rm.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	01 May 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2024
Global end of trial reached?	Yes
Global end of trial date	01 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Cytotoxicity of Yellow Fever specific CD8 T cells Following YF-17D Vaccination

Protection of trial subjects:

1. At time of vaccination, no fever as measured by oral temp >37.5 C
2. At time of vaccination, not received immunosuppressive therapy
3. Pregnancy test prior to vaccination
4. Exclusion of persons with immune defect, thymic dysfunction, disease in the blood system, allergic reaction towards vaccines and egg allergy

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 August 2019
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Persons interested in vaccination against yellow fever was approached for participation

Pre-assignment

Screening details:

Exclusion and inclusion criteria was confirmed

Period 1

Period 1 title	Study period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Arm title	Vaccine arm
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Arm description:

Vaccination with the live-attenuated yellow fever (YF) YF-17D vaccine (Stamaril, Novartis) to study vaccine-induced YF epitope-specific CD8+ T cell (YF CTL) responses

Arm type	Experimental
Investigational medicinal product name	Stamaril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

a single dose of 0.5 mL 17D live-attenuated YF vaccine (Stamaril, Sanofi Pasteur)

Number of subjects in period 1	Vaccine arm
Started	60
Completed	60

Baseline characteristics

Reporting groups

Reporting group title	Study period
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Reporting group description:

Healthy adult participants were recruited in the study (NCT04083430) and received vaccination with a single dose of 0.5 mL 17D live-attenuated YF vaccine (Stamaril, Sanofi Pasteur). Individuals self-reported any previous history of vaccination with YF-17D. Blood samples were taken (up to 100 days) prior to and at two timepoints (day 21 ± 3 and 100 ± 40) after vaccination

Reporting group values	Study period	Total	
Number of subjects	60	60	
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	26		
full range (min-max)	19 to 59	-	
Gender categorical			
Units: Subjects			
Female	41	41	
Male	19	19	

End points

End points reporting groups

Reporting group title	Vaccine arm
Reporting group description: Vaccination with the live-attenuated yellow fever (YF) YF-17D vaccine (Stamaril, Novartis) to study vaccine-induced YF epitope-specific CD8+ T cell (YF CTL) responses	

Primary: Quantification of vaccine-induced YF CTLs

End point title	Quantification of vaccine-induced YF CTLs ^[1]
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End point description:

End point type	Primary
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End point timeframe:

April 2019 to September 2024

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: These is purely a descriptive study

End point values	Vaccine arm			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: 79%	60			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

April 2019 to September 2024

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	5
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Reporting groups

Reporting group title	Adverse events
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Reporting group description: -

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

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

Non-serious adverse events	Adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 60 (11.67%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
Groin pain			

subjects affected / exposed occurrences (all)	1 / 60 (1.67%) 1		
Infections and infestations Pharyngitis subjects affected / exposed occurrences (all)	1 / 60 (1.67%) 1		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No major as this was descriptive

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/37672868>