Clinical trial results:
REgorafenib's Liquid BiopsY (RELY): A multicenter translational biomarker phase II trial of regorafenib in patients with non-resectable pretreated colorectal cancer.

a non-profit investigator-initiated trial

Summary

EudraCT number	2014-004927-27
Trial protocol	AT
Global end of trial date	01 February 2019

Results information

Result version number	v1 (current)
This version publication date	11 December 2025
First version publication date	11 December 2025

Trial information

Trial identification

Sponsor protocol code	RELAIS

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01983098
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedUniWien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Marika Rosner, MedUniWien, +43 14040044450, marika.rosner@meduniwien.ac.at
Scientific contact	Gerlad Prager, MedUniWien, +43 14040044450, gerald.prager@meduniwien.ac.at

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 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2019
Global end of trial reached?	Yes
Global end of trial date	01 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to investigate circulating tumor DNA (ctDNA) via deep sequencing for mutation detection and by whole genome sequencing for copy number analyses before start (baseline) with regorafenib and at defined time points during administration of regorafenib for treatment efficacy in colorectal cancer patients in terms of overall survival (OS).

Protection of trial subjects:

CT Thorax/Abdomen every 8 weeks

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 January 2015
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	Austria: 29
Country: Number of subjects enrolled	Switzerland: 1
Worldwide total number of subjects	30
EEA total number of subjects	29

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)	20
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In total 30 patient were enrolled in the trial - 25 in Vienna, 1 in Graz, 1 in Wels and 1 in Zurich.

Pre-assignment

Screening details:

30 patient were screened according to the inclusion and exclusion criteria

Period 1

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

Arms

Arm title	Treatment arm

Arm description:

single-arm study

Arm type	Experimental
Investigational medicinal product name	Regorafenib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Regorafenib in standard dose -160mg od po, 3weeks on/1 week off

Number of subjects in period 1	Treatment arm
Started	30
Completed	30

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	30	30	
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)	18	18	
From 65-84 years	12	12	
85 years and over	0	0	
Age continuous Units: years			
median	60		
full range (min-max)	33 to 78	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	20	20	

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Per protocol

Subject analysis set description:

Examination of the freely circulating tumor DNA (ctDNA) for mutations using deep sequencing and to determine the number of DNA copies using whole genome sequencing.

Reporting group values	Overall trial		
Number of subjects	30		
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)	18		
From 65-84 years	12		
85 years and over	0		
Age continuous			
Units: years			
median	60		
full range (min-max)	33 to 78		
Gender categorical			
Units: Subjects			
Female	10		
Male	20		

End points

End points reporting groups

Reporting group title	Treatment arm
Reporting group description: single-arm study	
Subject analysis set title	Overall trial
Subject analysis set type	Per protocol
Subject analysis set description: Examination of the freely circulating tumor DNA (ctDNA) for mutations using deep sequencing and to determine the number of DNA copies using whole genome sequencing.	

Primary: ctDNA via deep sequencing for mutation detection

End point title	ctDNA via deep sequencing for mutation detection
End point description: Real time tumor-tissue biopsy will (mandatory) be performed at baseline (within 4 weeks before start with regorafenib) and after 8 weeks (optional). Tumor tissue samples will be analyzed by deep sequencing and whole genome sequencing and results will be correlated to the liquid biopsy analysis and treatment efficacy parameters (see above). In addition, the baseline Immunoscore will be assessed and correlated to treatment efficacy.	
End point type	Primary
End point timeframe: within 4 weeks before , after 4 weeks and after 8 weeks start with regorafenib	

End point values	Treatment arm	Overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	30	30		
Units: ctDNA				
median (full range (min-max))	60 (33 to 78)	60 (33 to 78)		

Statistical analyses

Statistical analysis title	ctDNA for mutation detection
Comparison groups	Treatment arm v Overall trial
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0 [2]
Method	no p-value definied
Parameter estimate	Cox proportional hazard

Notes:

[1] - Univariate and multivariate semi parametric Cox models

[2] - no p-value definied

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
There are no records relating to AES	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

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

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: There are no records relating to AES

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 June 2015	For legal reasons, the short title of the study was changed from CRC-RELY to RELAIS
13 October 2015	Switzerland was added with 1 site

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported