



Clinical trial results:

Influence of an Acidic Beverage (Coca-Cola) on the exposure to Imatinib (GLivec) after major gastrectomy in patients with Gastrointestinal Stromal Tumors (ABILITY)

Summary

EudraCT number	2014-001044-38
Trial protocol	NL
Global end of trial date	03 November 2016

Results information

Result version number	v1 (current)
This version publication date	24 October 2019
First version publication date	24 October 2019
Summary attachment (see zip file)	ABILITY PAPER (ABILITY_paper_2017.pdf)

Trial information

Trial identification

Sponsor protocol code	UMCN-AKF14.01
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Radboudumc
Sponsor organisation address	Geert Grooteplein zuid 10, Nijmegen, Netherlands,
Public contact	David Burger, Radboud University Nijmegen Medical Center, david.burger@radboudumc.nl
Scientific contact	David Burger, Radboud University Nijmegen Medical Center, david.burger@radboudumc.nl

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	12 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 November 2016
Global end of trial reached?	Yes
Global end of trial date	03 November 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the effects of Coca-Cola on the exposure to imatinib in patients with major gastrectomy.

Protection of trial subjects:

The drug is licensed on the Dutch market for the dose administered. The only intervention is adding Coca-Cola to the dosing regimen, possibly increasing exposure to imatinib. There is no attributable risk for the application of the study protocol to the patients.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2014
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	Netherlands: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	7
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

patients with histologically confirmed GIST, who have undergone major gastrectomy and are currently treated or will start imatinib therapy were eligible

Period 1

Period 1 title	screening
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	screening
Arm description: -	
Arm type	screening
Investigational medicinal product name	imatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

none

Number of subjects in period 1	screening
Started	7
Completed	7

Period 2

Period 2 title	treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
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Arm title	imatinib alone
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	imatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
400-800mg daily	
Arm title	imatinib + coca cola
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	imatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
400-800mg + coca cola	

Number of subjects in period 2	imatinib alone	imatinib + coca cola
Started	7	7
Completed	7	7

Baseline characteristics

Reporting groups

Reporting group title	screening
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Reporting group description: -

Reporting group values	screening	Total	
Number of subjects	7	7	
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	62		
full range (min-max)	46 to 89	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	4	4	

End points

End points reporting groups

Reporting group title	screening
Reporting group description: -	
Reporting group title	imatinib alone
Reporting group description: -	
Reporting group title	imatinib + coca cola
Reporting group description: -	

Primary: AUC imatinib

End point title	AUC imatinib
End point description:	
End point type	Primary
End point timeframe:	whole trial

End point values	imatinib alone	imatinib + coca cola		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: mg*h/L				
geometric mean (confidence interval 95%)	25 (18 to 34)	26 (20 to 34)		

Statistical analyses

Statistical analysis title	geometric mean ratio
Comparison groups	imatinib + coca cola v imatinib alone
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	geometric mean ratio
Point estimate	1.04
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.14

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

entire study

Assessment type	Non-systematic
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Dictionary used

Dictionary name	none
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Dictionary version	1
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Reporting groups

Reporting group title	imatinib
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Reporting group description: -

Serious adverse events	imatinib		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	imatinib		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 7 (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 reported

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? Yes

Date	Interruption	Restart date
03 November 2016	Slow inclusion rates in this study as only a low number of patients with GIST have a gastrectomy, which was an inclusion criterium.	-

Notes:

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/28677263>