



## Clinical trial results: Cerebral effect of paracetamol measured by f-MRI Summary

EudraCT number	2013-004908-20
Trial protocol	BE
Global end of trial date	06 August 2024

### Results information

Result version number	v1 (current)
This version publication date	10 May 2025
First version publication date	10 May 2025

### Trial information

#### Trial identification

Sponsor protocol code	PARAMRI
-----------------------	---------

#### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	UZ Brussel
Sponsor organisation address	Laarbeeklaan, Brussel, Belgium,
Public contact	Datanurse, UZ Brussel, 32 24776001, virgini.vanbuggenhout@uzbrussel.be
Scientific contact	Datanurse, UZ Brussel, 32 24776001, virgini.vanbuggenhout@uzbrussel.be

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	30 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 April 2016
Global end of trial reached?	Yes
Global end of trial date	06 August 2024
Was the trial ended prematurely?	No

Notes:

---

**General information about the trial**

Main objective of the trial:

Evaluation of the cerebral activity of paracetamol, assessed by f-MRI

Protection of trial subjects:

All patients were followed up regarding safety from signing informed consent till end of study (second MRI).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 December 2013
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	Belgium: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

### Period 1

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

### Arms

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

Dosage and administration details:

1g of paracetamol was given once together with a glass of still water.

<b>Number of subjects in period 1</b>	MRI - paracetamol
Started	20
Completed	20

## Baseline characteristics

### Reporting groups

Reporting group title	MRI - paracetamol
-----------------------	-------------------

Reporting group description: -

Reporting group values	MRI - paracetamol	Total	
Number of subjects	20	20	
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	31		
full range (min-max)	22 to 55	-	
Gender categorical			
Units: Subjects			
Female	11	11	
Male	9	9	
weight			
Units: kilogram(s)			
median	75		
full range (min-max)	48 to 120	-	
height			
Units: centimetre			
median	176		
full range (min-max)	160 to 195	-	

## End points

### End points reporting groups

Reporting group title	MRI - paracetamol
Reporting group description: -	

### Primary: Ventral left cortex cerebellum posterior lobe

End point title	Ventral left cortex cerebellum posterior lobe <sup>[1]</sup>
End point description: Data were expressed as t-value subtraction versus baseline (before intake paracetamol).	
End point type	Primary
End point timeframe: Ventral Left cluster of the brain (cerebellum posterior lobe). Difference between first MRI and second MRI	

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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

End point values	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	117			

### Statistical analyses

No statistical analyses for this end point

### Primary: ventral left cortex middle temporal gyrus

End point title	ventral left cortex middle temporal gyrus <sup>[2]</sup>
End point description: Data were expressed as t-value subtraction versus baseline (before intake).	
End point type	Primary
End point timeframe: Ventral Left cluster of the brain (middle temporal gyrus). Difference between first MRI and second MRI	

Notes:

[2] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	85			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral left cortex posterior cingulate

End point title	ventral left cortex posterior cingulate <sup>[3]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

Ventral Left cluster of the brain (posterior cingulate). Difference between first MRI and second MRI.

Notes:

[3] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	576			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral left cortex caudata

End point title	ventral left cortex caudata <sup>[4]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

Ventral Left cluster of the brain (caudata). Difference between first MRI and second MRI.

Notes:

[4] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	93			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral right cortex temporal

End point title	ventral right cortex temporal <sup>[5]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

Ventral right cluster of the brain (Temporal). Difference between first MRI and second MRI.

Notes:

[5] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	103			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral right cortex posterior cingulate

End point title	ventral right cortex posterior cingulate <sup>[6]</sup>
-----------------	---

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

Ventral right cortex (posterior cingulate) difference between MRI before paracetamol and MRI after paracetamol.

Notes:

[6] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	185			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral right cortex superior frontal gyrus

End point title	ventral right cortex superior frontal gyrus <sup>[7]</sup>
End point description:	Data were expressed as t-value subtraction versus baseline (before intake).
End point type	Primary
End point timeframe:	Ventral right cortex (superior frontal gyrus). difference between MRI before paracetamol and MRI after paracetamol.

Notes:

[7] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	281			

## Statistical analyses

No statistical analyses for this end point

### Primary: dorsal left cortex temporal

End point title	dorsal left cortex temporal <sup>[8]</sup>
End point description:	Data were expressed as t-value subtraction versus baseline (before intake).
End point type	Primary
End point timeframe:	dorsal left cortex (temporal). Difference between MRI before paracetamol and MRI after paracetamol

Notes:

[8] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).



<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	239			

## Statistical analyses

No statistical analyses for this end point

### Primary: dorsal left cortex inferior frontal gyrus

End point title	dorsal left cortex inferior frontal gyrus <sup>[9]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

dorsal left cortex inferior frontal gyrus. Difference between MRI before paracetamol and MRI after paracetamol.

Notes:

[9] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	165			

## Statistical analyses

No statistical analyses for this end point

### Primary: dorsal right cortex- postcentral gyrus

End point title	dorsal right cortex- postcentral gyrus <sup>[10]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

dorsal right cortex postcentral gyrus. Difference between MRI before paracetamol and MRI after paracetamol.

Notes:

[10] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	102			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal left cortex insula

End point title	ventral and dorsal left cortex insula <sup>[11]</sup>
-----------------	---

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal left cortex insula. Difference between MRI before paracetamol and MRI after paracetamol.

Notes:

[11] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	212			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal left cortex middle frontal gyrus

End point title	ventral and dorsal left cortex middle frontal gyrus <sup>[12]</sup>
-----------------	---

End point description:

Data were expressed as t-value subtraction versus baseline (before intake).

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal left cortex middle frontal gyrus. Difference between MRI before paracetamol and MRI after paracetamol

Notes:

[12] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	85			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal left cortex posterior cingulate

End point title	ventral and dorsal left cortex posterior cingulate <sup>[13]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake)

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal left cortex posterior cingulate. Difference between MRI before paracetamol and MRI after.

Notes:

[13] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	149			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal left cortex precentral

End point title	ventral and dorsal left cortex precentral <sup>[14]</sup>
-----------------	---

End point description:

Data were expressed as t-value subtraction versus baseline (before intake)

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal left cortex precentral. Difference between MRI before paracetamol and MRI after.

Notes:

[14] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	880			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal right cortex temporal

End point title	ventral and dorsal right cortex temporal <sup>[15]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake)

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal right cortex temporal. Difference between MRI before paracetamol and MRI after

Notes:

[15] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	88			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal right cortex inferior frontal gyrus

End point title	ventral and dorsal right cortex inferior frontal gyrus <sup>[16]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake)

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal right cortex inferior frontal gyrus. Difference between MRI before paracetamol and MRI after

Notes:

[16] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	86			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal right cortex precentral gyrus

End point title	ventral and dorsal right cortex precentral gyrus <sup>[17]</sup>
-----------------	--

End point description:

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal right cortex precentral gyrus. Difference between MRI before paracetamol and MRI after.

Notes:

[17] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	105			

## Statistical analyses

No statistical analyses for this end point

### Primary: ventral and dorsal right cortex precentral

End point title	ventral and dorsal right cortex precentral <sup>[18]</sup>
-----------------	--

End point description:

Data were expressed as t-value subtraction versus baseline (before intake)

End point type	Primary
----------------	---------

End point timeframe:

ventral and dorsal right cortex precentral. Difference between MRI before paracetamol and MRI after.

Notes:

[18] - 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: Measurements were done in the same arm. Patient had a MRI before given paracetamol and one MRI after. Data were expressed as t-value subtraction versus baseline (before intake).

<b>End point values</b>	MRI - paracetamol			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Kelvin	708			

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

adverse events were reported from signing the informed consent till the second MRI was done.

Assessment type	Systematic
-----------------	------------

### Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	22
--------------------	----

### Reporting groups

Reporting group title	Study conduct
-----------------------	---------------

Reporting group description: -

Serious adverse events	Study conduct		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (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	Study conduct		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (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: safety was assessed after ICF was signed. However, patients only had to come in for the study one day, they had to perform a MRI, take a paracetamol afterwards and did another MRI. After that they've reached the end of the 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