EU Clinical Trials Register

Clinical trial results:
CICA-RT – Phase III randomized multicenter study evaluating Cicaderma® ointment efficacy versus the current practice of each center for the radiation dermatitis prevention in patients with non-metastatic breast cancer after adjuvant post-operative breast irradiation

Summary

EudraCT number	2019-001711-23
Trial protocol	FR
Global end of trial date	01 July 2021

Results information

Result version number	v1 (current)
This version publication date	06 November 2022
First version publication date	06 November 2022
Summary attachment (see zip file)	RRF (2019-001711-23_CiCA-RT.pdf)

Trial information

Trial identification

Sponsor protocol code	ET19-084

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Centre Léon Bérard
Sponsor organisation address	28 rue Laennec, Lyon Cedex 08, France, 69373
Public contact	Séverine METZGER, Centre Léon Bérard, +33 4 78 78 28 28,
Scientific contact	Dr Séverine RACADOT Pr Youlia KIROVA, Centre Léon Bérard, +33 4 78 78 28 28,

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	05 November 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of Cicaderma® ointment versus the standard care of each center in the prevention of grade > 2 radiation dermatitis according to National Cancer Institute – Common Terminology Criteria for Adverse Events-Version (NCI-CTCAE-V5)

Protection of trial subjects:

The investigator proceeded to the following information/procedures during the screening visit:
- Fully inform the patient of the study treatments, the objectives and the design of the study, answer to any questions that the patient may have and ensure that the patient understands the potential risks and benefits of participating in the study before signing the informed consent form. None study-related procedure can be started before ICF is signed and dated by both the patient (and impartial witness, if applicable).
- Check the eligibility criteria list and perform the exams.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 June 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 258
Worldwide total number of subjects	258
EEA total number of subjects	258

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)	148

From 65 to 84 years	80
85 years and over	30

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the time of enrolment at the participating sites. The declared investigator, after having identified a potential candidate for the study, informed her orally of the terms of the study and provide her with : an information note, An informed consent form that has been dated and signed by the patient and the investigator.

Pre-assignment

Screening details:

None study-related procedure can be started before ICF was signed and dated by both the patient (and impartial witness, if applicable) and the investigator - Checked the eligibility criteria list and perform the exams.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Hygiene rules and preventive treatment with Cicaderma®

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Cicaderma®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Route of administration not applicable

Dosage and administration details:

2 applications per day for 30 days

Arm title	Arm B: Standard Pratice

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Arm A: Hygiene rules and preventive treatment with Cicaderma®	Arm B: Standard Pratice
Started	130	128
Completed	130	128

Baseline characteristics

Reporting groups

Reporting group title	Arm A: Hygiene rules and preventive treatment with Cicaderma®
Reporting group description: -	
Reporting group title	Arm B: Standard Pratice

Reporting group description: -

Reporting group values	Arm A: Hygiene rules and preventive treatment with Cicaderma®	Arm B: Standard Pratice	Total
Number of subjects	130	128	258
Age categorical			
Units: Subjects			
22-91 years	130	128	258
Age continuous			
Units: years			
median	60.0	62.0	
full range (min-max)	31 to 91	22 to 86	-
Gender categorical			
Units: Subjects			
Female	130	128	258

Subject analysis sets

Subject analysis set title	Primary endpoint in Cicaderma arm
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intention-to-treat (ITT) population: defined as all patients randomised, regardless of treatment received and study conduct. Patients will be analysed according to their initial randomisation group, regardless of the actual treatment received.

Subject analysis set title	Primary endpoint in standard practice arm
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intention-to-treat (ITT) population: defined as all patients randomised, regardless of treatment received and study conduct. Patients will be analysed according to their initial randomisation group, regardless of the actual treatment received.

Reporting group values	Primary endpoint in Cicaderma arm	Primary endpoint in standard practice arm	
Number of subjects	130	128	
Age categorical			
Units: Subjects			
22-91 years			
Age continuous			
Units: years			
median	60.0	62.0	
full range (min-max)	31 to 91	22 to 86	

Gender categorical Units: Subjects			
Female	130	128	

End points

End points reporting groups

Reporting group title	Arm A: Hygiene rules and preventive treatment with Cicaderma®
Reporting group description: -	
Reporting group title	Arm B: Standard Pratice
Reporting group description: -	
Subject analysis set title	Primary endpoint in Cicaderma arm
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intention-to-treat (ITT) population: defined as all patients randomised, regardless of treatment received and study conduct. Patients will be analysed according to their initial randomisation group, regardless of the actual treatment received.

Subject analysis set title	Primary endpoint in standard practice arm
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intention-to-treat (ITT) population: defined as all patients randomised, regardless of treatment received and study conduct. Patients will be analysed according to their initial randomisation group, regardless of the actual treatment received.

Primary: Efficacy Primary endpoint

End point title	Efficacy Primary endpoint

End point description:

End point type	Primary

End point timeframe:

30 days

End point values	Arm A: Hygiene rules and preventive treatment with Cicaderma®	Arm B: Standard Pratice	Primary endpoint in Cicaderma arm	Primary endpoint in standard practice arm
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	130	128	130	128
Units: ≥2	130	128	130	128

Statistical analyses

Statistical analysis title	Efficacy Primary endpoint
Comparison groups	Arm B: Standard Pratice v Arm A: Hygiene rules and preventive treatment with Cicaderma®

Number of subjects included in analysis	258
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	= 1
Method	Chi-squared

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The investigator collects (spontaneous patient report or questionning) and immediately notifies the sponsor of all SAEs, in a written report, wether or not theay are deemed to be attributable to research and wich occur during the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

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

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: Non-serious events were collected and not specifically reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 June 2020	- Implementation of an urgent safety measure following COVID-19. A letter dated 27 May 2020 mentioning this notification was sent to the authorities on 28 May 2020.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
27 May 2020	- Implementation of an urgent safety measure (USM) following COVID-19. A letter dated 27 May 2020 mentioning this notification was sent to the authorities on 28 May 2020.	-

Notes:

Limitations and caveats

None reported