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TTFields In Germany in routine clinical care

Submission date
27/07/2017

Recruitment status
No longer recruiting

Registration date
08/08/2017

Overall study status
Completed

Last Edited
21/02/2023

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Glioblastoma (GBM) is the most common malignant primary tumor (cancer) of the brain. The current standard of care for patients with newly diagnosed GBM consists of maximal surgical resection (surgically removing the cancer), radiotherapy together with chemotherapy using temozolomide (TMZ), followed by maintenance TMZ for six months. This treatment scheme was shown to extend median survival from 12.1 to 14.6 months compared to surgery and radiotherapy alone. This survival was essentially unchanged since 2005 despite numerous other studies. Although immense efforts have been made over the years with different treatment strategies, the survival of patients with newly diagnosed GBM remained very poor until recently. Tumor-treating fields (TTFields) are low-intensity, intermediate frequency, alternating electric fields delivered continuously through adhesive patches, called transducer arrays, to the area of the brain where the GBM tumor is located and help slow down or stop glioblastoma cancer cells from dividing. These transducer arrays are applied to the scalp and are connected to the wearable and portable device. The aim of this study is to collect real life data on the use of tumor-treating fields (TTFields) in patients with newly diagnosed GBM in routine clinical care in Germany.

Who can participate?
Patients aged 18 and older who have GBM

What does the study involve?
This study is a chart review study. Participants who receive TTFields treatment have data collected about their care for 24 months. Data is collected about their health and any serious adverse events that occurred during their care. Participants complete a quality of life questionnaire and questionnaire about TTFields at baseline and during their follow up treatment.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating

Where is the study run from?
This study is being run from 5 hospitals in Germany

When is the study starting and how long is it expected to run for?
July 2017 to August 2022

Who is funding the study?
Novocure GmbH (Germany)

Who is the main contact?
1. Dunja Kosanovic
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2. Prof. Dr Oliver Bähr

Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03258021

Protocol serial number
05.07.2017

Study information

Scientific Title
TTFields In GErmany in Routine clinical care (TIGER): the use of TTFields for newly diagnosed GBM patients in Germany in routine clinical care

Acronym
TIGER

Study objectives
The purpose of this post-authorisation medical device study is to obtain real life data on the use of tumor-treating fields (TTFields) in patients with newly diagnosed GBM in routine clinical care in Germany.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission des FB Medizin der J.W. Goethe-Universität, 23/08/2017, ref: 280/17

Primary study design
Observational

Study design
Multicentre prospective non-interventional observational post-authorisation medical device study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glioblastoma

Interventions
This is non-interventional study evaluating use of tumor-treating fields (TTFields) in newly diagnosed glioblastoma (GBM) patients in routine clinical care. TTFields help slow down or stop glioblastoma cancer cells from dividing by disrupting dividing mechanism of cancer cells leading to apoptosis. TTFields are low-intensity, intermediate frequency, alternating electric fields delivered continuously through adhesive patches, called transducer arrays, to the area of the brain where the GBM tumor is located. These transducer arrays are applied to the scalp and are connected to the wearable and portable device. TTFields are approved for the treatment of newly diagnosed and recurrent GBM.

Eligible participants are enrolled in the study after signing informed consent to use their data and process it centrally for research purposes. Participants do not experience any tests or procedures that are not part of routine clinical care. For patients refusing TTFields treatment at baseline only baseline data is collected. Patient who initiate TTFields Therapy are followed-up during the first 24 months after study enrolment, LPI has a max. of 18 months follow-up.

Data obtained from patient files: Only data which can be obtained from routine clinical care files of the patients is recorded. Data of each routine clinical care visit during the first 24 months after study enrolment is reported in the eCRF. Data is derived from clinical records and findings, radiological assessments (e.g. contrast enhanced MRI), observations or other sources (e.g. hospital records, clinical and office charts, electronic patient records, laboratory notes, recorded data from automated device). Serious Adverse Events (SAEs) are documented during follow-up visits by the treating investigator and subsequently centrally assessed by an independent Clinical Event Committee.

Participants also complete quality of life questionnaires and a study-specific questionnaire on TTFields at baseline and during follow-up.

Intervention Type
Other

Primary outcome(s)
1. Time to death of any cause (overall survival [OS]) from diagnosis is measured using the patient data from date of enrollment until the date of death from any cause
2. Number of TTFields treatment-related (serious adverse events) SAEs standardised to one year of FU is measured using the collection of SAEs during the follow-up period
3. Number of SAEs after start of TTFields treatment is measured using the collection of SAEs at the follow-up period
4. Time of usage (compliance) of TTFields treatment over time is measured using the treatment compliance report at the follow-up period
5. Time to first progression of GBM (progression-free survival [PFS]), defined within radiological and/or clinical/neurological assessment during routine clinical care in patients who started TTFields treatment at baseline from date of enrollment until the date of first progression of GBM
6. Changes in quality of life after start of TTFields treatment compared to baseline in patients who started TTFields treatment at baseline is measured using the QoL questionnaires at months two and four after start of TTFields treatment
7. Patients' reason(s) for refusing TTFields is measured using a questionnaire at baseline

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Newly diagnosed histologically confirmed GBM (WHO-Grade IV)
2. Patient within first 3 cycles of first-line tumor-specific maintenance chemotherapy
3. ≥ 18 years of age
4. Clinical indication for TTFields treatment
5. Given informed consent for use and processing of data

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
709

Key exclusion criteria
1. Present or planned pregnancy
2. Significant additional neurological disease (e.g. significantly increased intracerebral pressure (ICP) with a significant midline shift of the brain)
3. Active implanted medical device (e.g. deep brain stimulator)
4. Documented allergy to conductive hydrogel
5. Skull defect (e.g. missing bone with no replacement, bullet fragments in the skull)

Date of first enrolment
31/08/2017

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Germany

Study participating centre
Clinical Centre Aschaffenburg
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63739

Sponsor information

Organisation
Novocure GmbH

ROR
https://ror.org/04pspdc11

Funder(s)

Funder type
Industry

Funder Name
Novocure GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection.

IPD sharing plan summary
Not expected to be made available