Exploring the immunological competence of the meninges and bone marrow in neurological diseases

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Identifying the (immune) cell composition, co-localization, functions, and alterations as well as blood and lymph vessels reorganisation in the human*s dura, arachnoid and pia mater, and skull bone marrow in high-grade glioma patients as compared to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON56851

Source
ToetsingOnline

Brief title
ENDURE

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system, skull and spine therapeutic procedures

Synonym
Glioblastoom, glioom

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Stichting STOPHersentumoren.nl

Intervention

Keyword: Glioma, Immunology, Meninges, Skull bone marrow

Outcome measures

Primary outcome

Differences in (immune) cell composition (type of immune cells and abundance) and behaviour (as measured by gene and protein expression profiles and cell localization) of the meninges and skull bone marrow between patients with high-grade glioma and non-glioma controls.

Secondary outcome

Tissues will be made part of a biobank.

Study description

Background summary

The brains meninges, i.e. the physical layers surrounding the brain (dura mater, arachnoid mater, and pia mater), as well as the overlaying skull bone marrow are a rich source of immunological cells and lymphoid tissues. These layers and tissues are in close connection and rapidly respond to processes within the brain, esp. in the case of infections, neuro-inflammation, or tumor growth. We hypothesize that this immune function is disturbed in patients with a high-grade glioma, one of the most malignant brain tumors. In-depth characterization and knowledge on the composition of immune and supportive cells, including blood and lymph vessels, within these tissues can provide novel leads to develop treatments for neuro-oncological diseases such as gliomas. This may also result into valuable knowledge and therapy-development for other neurological diseases, including multiple sclerosis and Alzheimer*s disease, hemorrhagic neurological diseases such as subarachnoid and (traumatic) intracranial hemorrhages, central nervous system infections, medically-intractable epilepsy, and other congenital or acquired neurological conditions.

Study objective

Identifying the (immune) cell composition, co-localization, functions, and

alterations as well as blood and lymph vessels reorganisation in the human*s dura, arachnoid and pia mater, and skull bone marrow in high-grade glioma patients as compared to non-glioma controls.

Study design

Investigator-initiated observational study.

Study burden and risks

As participants are already subjected to a neurosurgical operation due to their primary clinical condition, the additional burden of this study is the collection of additional tissue on top of that required for primary clinical care. The skull bone marrow will be collected by small biopsies from easily reachable exposed bone. A sample of dura mater will be collected and replaced by autologous duraplasty (i.e. pericranium/periosteal layer) as is already a standard procedure in approximately 50 % of cranial intradural neurosurgical operations. Pia and arachnoid mater will only be collected if the brain*s cortex needs to be entered because of deeper-seated intraparenchymal lesions, and their removal is thus already part of the operative route. From patients of whom during the operation a duraplasty has to be created, and of whom dura mater has to be reduced to simplify integration of the duraplasty, the left-over dura mater is collected for this study (*rest-materiaal*). From this particular group of patients, skull bone marrow is collected from left-over bone splinters generated with placing the burr hole for skull trephination, or from the bone flap when left-out (craniectomy; both *rest-materiaal*). All material will be collected pseudonymously, and there will be no follow-up visits. The estimated risk from collecting skull bone marrow, and pia, arachnoid and dura mater is considered moderate. There are no benefits to the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 18 years of age, or older
• Subjected to a neurosurgical intracranial operation

Exclusion criteria

- Participants of whom the required tissues cannot be accessed due to the operative route and strategy or of whom the tissue cannot be safely collected, including individuals of whom no autologous duraplasty can be harvested.
- Individuals with inherent bleeding disorders.
- Individuals with an inherent or acquired immunodeficiency and/or medications that suppress wound healing (except dexamethasone).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-05-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85472.018.23