The Clinical Usefulness of the PANOMEN 3 Grade Score

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Study Planned

Administrative details

EU PAS number

EUPAS1000000488

Study ID

1000000488

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Bulgaria
- [ ] Denmark
- [ ] European Union
- [ ] Finland
- [ ] France

- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Romania
- [ ] Spain
- [ ] Sweden

Study description

The second Pituitary Neoplasm Nomenclature workshop (PANOMEN 2), initiated by the Pituitary Society, addressed the need for a comprehensive classification system that could guide prognosis and therapy of all pituitary adenomas (Ho et al. 2023) The PANOMEN 3 clinical classification Workshop has proposed an all-inclusive classification system by integrating clinical, genetic, biochemical, radiological, pathological, and molecular data (Ho et al. 2024). Evidence-based risk factors that are associated with increased morbidity and mortality were included in the classification. A corrected score is calculated dependent on the amount of risk factors assessed and converted into a ranked grade of 0 to 3. These rank grades are hypothesized to be able to reflect disease severity together with a morbidity and mortality risk range. Until now, this classification system has not been applied to a cohort of patients with pituitary adenomas, also not during the stage of conceptualization. Therefore, the discriminative potential together with the clinical usefulness of the system is yet unknown.

The primary aim is to evaluate the clinical usefulness of the PANOMEN 3 Grade score in patients with all types of pituitary adenomas seen at Endo-ERN Reference Centers.

Study status

Planned

Research institutions and networks

Institutions

Amsterdam UMC

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Networks

European Reference Network on Rare Endocrine Conditions (endo-ERN)

Contact details

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Study timelines

Date when funding contract was signed
Planned: 01/10/2023

Study start date
Planned: 14/10/2024

Date of final study report
Planned: 01/03/2027

Sources of funding

- EU institutional research programme

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Clinical utility of proposed PANOMEN 3 grade score

Data collection methods:

Secondary use of data

Study design:

For this study, data is collected both retrospectively and prospectively using the Core Registry and the Condition Specific Pituitary Tumour Module of the European Registries for Rare Endocrine Conditions (EuRRECa; Workpackage 5 of Endo-ERN).

Main study objective:

The primary aim is to evaluate the clinical usefulness of the PANOMEN 3 Grade score in patients with all types of pituitary adenomas seen at Endo-ERN Reference Centers.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Patients with any type of pituitary adenomas (functioning and non-functioning) seen and/or treated at Endo-ERN Reference Centers.

Age groups

- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

(1) Patients seen and/or treated at Endo-ERN Reference Centers who are registered in the Core Registry and Pituitary Tumour Module (no age restriction);

(2) With the Primary Condition of Pituitary Adenoma (Index 1.23; 7.1) (Includes

the following Specific Diagnosis: Pituitary adenoma, Cushing disease, Familial isolated pituitary adenoma, Functioning gonadotropic adenoma, Functioning pituitary adenoma, Mixed functioning pituitary adenoma, Non-functioning pituitary adenoma, Null pituitary adenoma, Prolactinoma, Silent pituitary adenoma, Somatomammotropinoma, TSH-secreting pituitary adenoma, Acromegaly, X-linked acrogigantism, Pituitary carcinoma
(3) Who received their diagnosis after 01-01-2015 (Index 1.22)

Outcomes

Primary outcomes are the associations between the Grade scores at the time of diagnosis and at six months after a potential first surgery and tumour specific and general (co)morbidities, and HRs of Grade 1, 2, and 3 at time of diagnosis and six months after a potential first surgery in reference to Grade 0 for the following tumour specific (co)morbidities:

• Tumour growth/regrowth (event)
• Biochemical remission (in patients with functioning pituitary adenomas) (event)
• Biochemical recurrence (in patients with functioning pituitary adenoma in remission) (event)
• First surgery (event)
• Second surgery (in patients who have received a first surgery) (event)
• Medical therapy (event)
• Radiotherapy (event)
• Clinical apoplexy (event)
• Radiological apoplexy (event)

Data analysis plan

Descriptive data (n/N (%), mean ± SD, median (IQR)) will be analyzed, dependent on data structure and normality, by Chi-square test or Fisher’s exact test, One way ANOVA (followed by post-hoc tests to identify differences

between two specific groups), and Kruskal Wallis test (by post-hoc tests to identify differences between two specific groups).

Potential differences in prevalences of comorbidities at the time of the calculated PANOMEN 3 Grade scores will be evaluated by Chi-square tests and by calculating odds ratios (ORs) via logistic regression analysis.

Time-to-event data will be analyzed by Kaplan-Meier Survival Curves and Log-Rank tests, followed by Simple Cox Regression analysis to assess the unadjusted HR per Grade in reference to Grade 0.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No