The UK Cranioplasty Study – Outline

Project leads

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Project summary

The UK Cranioplasty Study will be a prospective study of indications, timing, material, technique and outcomes for cranioplasty across the UK. The study will be run from 1st June 2019 for six months followed by interim evaluation prior to potential extension with the intention of establishing a registry for cranioplasty in the UK for ongoing reporting.

Background

There has been an increased utilisation of decompressive craniectomy in the last decade, largely due to its application in stroke and traumatic head injury. Reconstruction of the skull is an important sequelae of this, and thus debate concerning the optimisation of outcome from cranioplasty exists. Multiple meta-analysis have been published investigating the optimal time following craniectomy,[1–5] which material should be used,[4,6,7] and factors associated with complications including infection, post-operative haematomas and hydrocephalus.[2,4]

In the UK alone, there exists a wide range of data on the morbidity and indeed mortality associated with cranioplasty. Data published in this area tends to be from a limited range of surgeons within one neurosurgical unit, is collected retrospectively and varied in data points and outcomes reported. There are currently no UK national guidelines on performing cranioplasty nor any defined patient outcome measures that should be reported by units. In 2013, the UK Cranial Reconstruction Registry (UKCRR) Collaborative Group published a proposal for the establishment of a registry to optimise outcomes of patients undergoing cranioplasty.[8]

The UK Cranioplasty Study is a time-limited study designed to enable the collection of prospective data across all units performing cranioplasty in the United Kingdom. The study will form the basis of a registry designed to enable ongoing data collection and monitoring to optimise care for patients undergoing this procedure.

Methods

Study Design

The UK Cranioplasty Study is a multicentre prospective study, collecting admission and 30-day outcome data for all patients undergoing a cranioplasty. The study will run initially over six months from 1st June 2019 with possible extension depending on results of interim analysis and centre engagement. The objectives of the study are to:

1. Monitor the demography, contemporary practice patterns including materials and timing, long-term clinical outcome and complication rates of cranioplasty across the UK.
2. Create pilot data for an ongoing cranioplasty registry for long-term surveillance to manufacturers (commercial and in-house), clinicians, healthcare planners, regulatory authorities and other stakeholders.

Inclusion criteria

1. Any patient undergoing reconstruction of the skull vault with autologous bone, titanium or synthetic material in participating units
2. Procedure performed from 1st June 2019
3. Primary or revision cranioplasty on an elective or emergency basis

Exclusion criteria

1. Patients undergoing craniosynostosis repair
2. Patients having a combined procedure (e.g. tumour excision with skull reconstruction, titanium mesh “cranioplasty” following skull base approaches)

Outcomes
Primary – 30-day mortality, reoperation rate and indication
Secondary – 30-day complication rate (superficial SSI, deep SSI, intracranial SSI, intracranial haematoma, hydrocephalus, escalation of care, subdural fluid collection, seizure, cranioplasty-related readmission), length of stay

Data Collection
Patients will be identified from elective and emergency neurosurgical operating lists and data entered into secure data collection form on ORION (Outcome Registry Intervention and Operation Network, www.orioncloud.org). Data fields are shown in Appendix A. Data completeness and validation will be performed using OPCS coding in each centre and HES data nationally.

Information Governance
Each unit will apply for local approval as a prospective audit including Caldicott guardian approval as required. The ORION platform complies with the Department of Health Information Governance policies and standards for secure processing of patient healthcare data as set out in the Information Governance Toolkit of the Health and Social Care Information Centre. The UK Cranioplasty Study will be implemented within the established ORION governance and administration structure. Each participating unit will be the data controller for its own submitted data, whilst the BNTRC will be responsible for coordinating national analysis of anonymised data. The BNTRC will have the overall responsibility for data validation, case ascertainment and oversight of the study.

Funding
There will be no costs to participating centres. The funding of the registry for long-term sustainability will be co-ordinated through the Brain Injury MedTech Co-operative.

Study Execution

Analysis plan
Data will be summarised over the six-month period according to material, time interval after craniectomy and patient characteristics including indication. Description of outcomes after cranioplasty (including implant survival and risk-adjusted complication rate) in the UK and Ireland for the preceding years will be presented across centre, material type and manufacturer. Description of data completeness at unit level will be published through comparison of submitted data to the NHS Hospital Episodes Statistics service in England and the Patient Episode Database in Wales.

Authorship Policy
Neurosurgical trainees will be recruited as local Project Investigators (PIs) for the UK Cranioplasty Study, with recognition as collaborator status authorship on the final publication.

Dissemination
The study findings will be disseminated in national and international conferences, and peer-reviewed publications.

Project Timeline

	Mar'19	Apr'19	May'19	Jun'19	Jul'19	Aug'19	Sep'19	Oct'19	Nov'19	Dec'19
Recruitment	■									
ORION registration		■								
Training			■							
Study period				■	■	■	■	■	■	
Data cleaning										■
Statistical analysis										■
Presentation and publication										■

Conclusion

The UK Cranioplasty Study will be the first multicentre study collecting admission and 30-day outcome data for patients undergoing cranioplasty in the UK. The study will form the basis of an ongoing registry to identify ways to improve our practice for patients undergoing this procedure.

References

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Appendix – Data Collection Fields on ORION

Domain	**Field**
Demographics	Unit
	Name
	Hospital number
	Sex
	DOB
	NHS number
Craniectomy	Date of craniectomy
	Procedure type (new insertion, removal, revision)
	Physical status
	Indication
	Current GCS
Cranioplasty	Knife to skin
	Final suture
	Primary surgeon
	Grade of primary surgeon
	Responsible consultants
	Total number of surgeons
	Material
	Manufacturer
	Serial number
	Other information
Intra-op	Location
	Wound drain inserted
Post-op	Post-op antibiotic prophylaxis
	Include note
30-Day Outcome	Length of stay
	Re-operation including indication
	Complication (superficial SSI, deep SSI, intracranial SSI, intracranial haematoma, hydrocephalus, escalation of care, subdural fluid collection, seizure)
	Cranioplasty-related readmission
	Mortality (date, plate removed, cause of death)