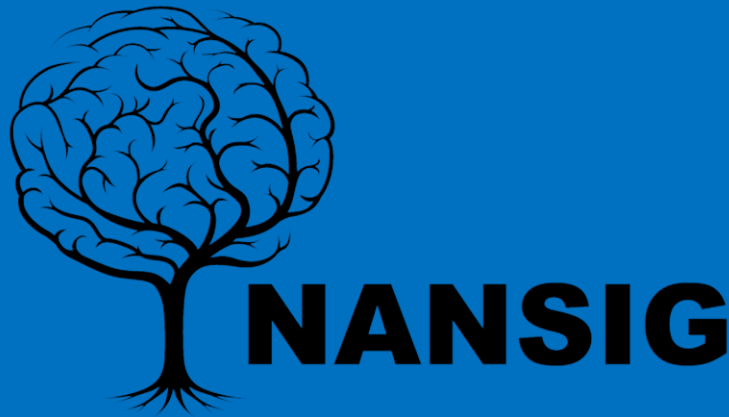


**CRANIAL: CSF Rhinorrhoea After Endonasal
Intervention to the Anterior Skull Base – A National
Prospective Service Evaluation on Incidence and
Management**

A 'How to' guide with practical tips



Project Background:

- **CSF leak** remains the most common complication of endoscopic endonasal surgery of the skull base.
- Reported incidence is very variable, with no national standard yet established.
- One of the critical determining factors of leak rates is the method of the **skull base reconstruction**.
- There is significant heterogeneity in current practice with no established national standards for CSF leak prevention and repair.
- Therefore we hope this **multicentre, prospective, clinical service evaluation** will help to inform national benchmarks in future.

Project Aim:

We aim to prospectively evaluate contemporary practice and outcomes of:

- Patients undergoing **endonasal (endoscopic or microscopic) transsphenoidal surgery** for sellar tumours (e.g. pituitary adenomas)
- Patients undergoing an **expanded endoscopic endonasal surgery** for skull base tumours (e.g. giant pituitary adenomas, craniopharyngiomas, meningiomas, chordomas, etc.)

Looking at which methods of skull base repair are used and the corresponding rates of CSF rhinorrhoea.

This will happen over a prospective 6-12 month period (6 months recruitment, 6 months follow-up ideally)

Why be involved?

- Contribution to a **collaborative, international** service evaluation, which will be evidenced by **certificates**.
- Facilitates **learning and mentorship** amongst junior trainees/students who will receive a lot of close senior support during the project.
- Collaborator status on the project **publication(s)**, with an opportunity to apply for contribution to the manuscript and full authorship.
- Opportunity to **present** the local service evaluation findings **at local audit meetings/equivalent**.

Local Process i)

- First apply to be a local CRANIAL lead via:
<https://forms.gle/XPyFy2a9hDoFynaR6>
- Medical students and junior doctors (in training or clinical fellow) are eligible to apply from participating centres. Please see the list of eligible centres with consultant pre-approvals on this google form.
- Local teams will be selected by local consultants and the CRANIAL management committee. They will be sent a welcome pack to aid local set up.
- Next, register the service evaluation and gain Caldicott guardian approval (usually integrated).
 - Local processes will vary but there is an example proforma in the material you have been sent.
- Meet your team if possible (student lead(s), trainee lead(s) and consultant(s))

Local Process ii)

- Email cranialnansig@gmail.com with service evaluation/Caldicott guardian approvals.
- We will send you your team CASTOR log in details so you can start uploading details onto CASTOR, our chosen data collection system.
- Remember to keep a separate identifiable log of patients incase this needs to be accessed later.
 - See slide 14.
- Full details of the process can be found in our Local Lead Document (on our website) and Protocol – please review these before starting.

Teamwork: Roles:

- Student leads [**must have access to the clinical portal at their local trust**]:
 - Registers service evaluation.
 - Assists local data collection (e.g. gathers operative lists and identifies relevant cases each week)
 - Seeks support and mentorship from senior team members regularly.
 - Keeps a strict and accurate patient code identifier sheet.
- Trainee leads (neurosurgical ST trainees or clinical fellows):
 - Provides day-to-day support to local student lead(s).
 - Leads in data collection and maintains data accuracy (they must review all data points collected by medical students on Castor).
 - Confirms critical data points (slide 18) with the operating surgeon(s)
- Local supervising consultant(s):
 - Approves and oversees service evaluation
 - Meets with local CRANIAL lead for: mid-point review (3 month) and end-of-recruitment review (6 month) and end of project review (9-12 months).
 - Provides support and guidance as necessary.

Teamwork: Process:

- The strength of the local team is integral to the success of CRANIAL.
- We encourage frequent communications (e.g. via WhatsApp, email or in person), particularly to support junior members of the data team.
- 3 month (halfway), 6 month (end of recruitment) and 12 month (end of project) meetings must happen and must include the CRANIAL local data leads and local supervising consultant at least (ideally all team members would be present).
- During our pilots, we found that collecting queries (data points that need confirmation) for each case on a secure document which can be sent to or discussed with operating surgeons periodic lumpsums was an efficient method of ensuring data accuracy.
- Try using our illustrations & definitions document to better understand skull base repair techniques and the terminology we are using for the project

Process Summary

Successful application to be a CRANIAL local project lead.

Initial team meeting

Secure local service evaluation approval and Caldicott guardian approval.

Contact cranialnansig@gmail.com confirming local service evaluation approvals (including Caldicott guardian approval).

Access CRANIAL's Castor page.

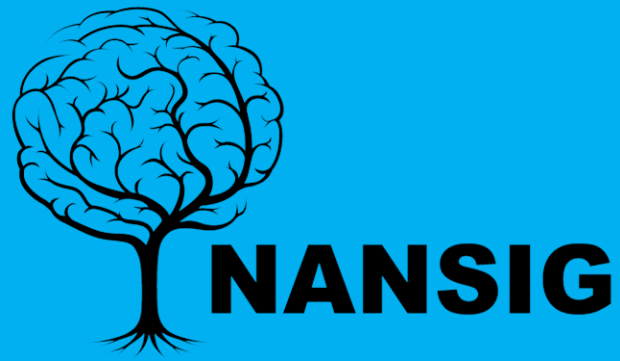
Upload data as-you-go onto Castor.
Keep a coded identifier sheet which corresponds local Castor data entry IDs to patient IDs - data governance principles must be strictly upheld when creating & storing this sheet.

Meet local consultants at 3 months (recruitment half-way mark), 6 months (recruitment end) and 9-12 months (follow-up end) to keep track of progress and troubleshoot any issues.

Send your team's completed collaborator checklist to our email address to sign off on data.

Be listed as a collaborator on all published CRANIAL materials.

Optional: Present your data at your local meeting meeting (please email us if you are considering presenting the data elsewhere).



The CRANIAL Project

A Practical Guide to:



Set up your CASTOR accounts

- Each collaborator will be given a unique account with login details. These details will be assigned to you after you register your local team
- If there are any problems then contact the CASTOR administrator or email cranialnansig@gmail.com

Login Page:

<https://uk.castoredc.com>

castor

Log in UK Server

Email

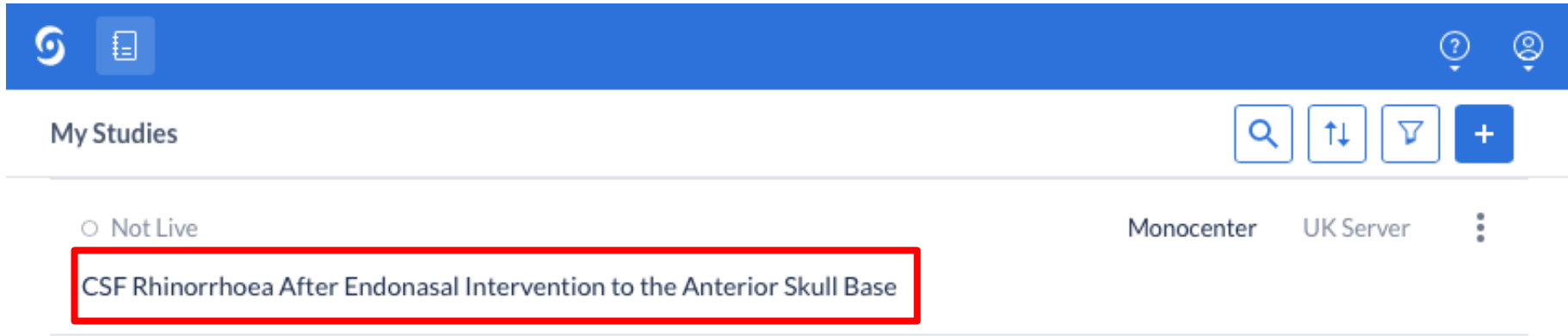
Password [Forgotten your password?](#)

Remember me

New to Castor? [Sign up here](#) →

Be sure to select the UK server

On 'My Studies', please select CRANIAL



The screenshot shows the 'My Studies' interface. At the top, there is a blue header bar with a search icon, a document icon, a help icon, and a user profile icon. Below the header, the text 'My Studies' is displayed on the left, and search, sort, filter, and add buttons are on the right. Underneath, there is a filter for 'Not Live' and two server options: 'Monocenter' and 'UK Server'. A single study is listed, titled 'CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base', which is highlighted with a red rectangular box.

In the 'Records' tab, select '+New record'

CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base ◦ Not Live (v.37.01)

Search: in **Record** Exact match



+ New record

View mode:

Progress by steps

Filter by record status:

- Completed records
- Incomplete records
- Not started
- Archived records

Filter by institute:

- All institutes
- University of Cambridge
- Test Institute

Record	1	2	3	4	5
000004 Test Institute	■	■	■	■	■
000005 Test Institute	■	■	■	■	■

This area will display your previous records and their completion status – use view mode “Progress by steps” for this:
Green – Complete
Yellow – Incomplete
Grey – Not started

Selecting your Institute will automatically generate a unique Record ID (000006 in this case)

Record	1	2	3	4	5
00004 Test Institute	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
00005 Test Institute	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New record details ×

Institute:

Record ID:



CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base

Not Live

Search: 000006

in Record

Exact match

View mode:

Progress by steps

Filter by record status:

- Completed records
- Incomplete records
- Not started
- Archived records

Filter by institute:

- All institutes
- University of

Record	1	2	3	4	5
000006					
Test Institute					

Baseline - not started

Double click the grey boxes to launch that part of the form

There are 5 forms to fill for each record. Hovering over the grey boxes/numbers will tell you what the different forms are:

- 1 – Baseline
- 2 – Operative
- 3 – Post-operative
- 4 – 6 month follow up
- 5 – Confirmation

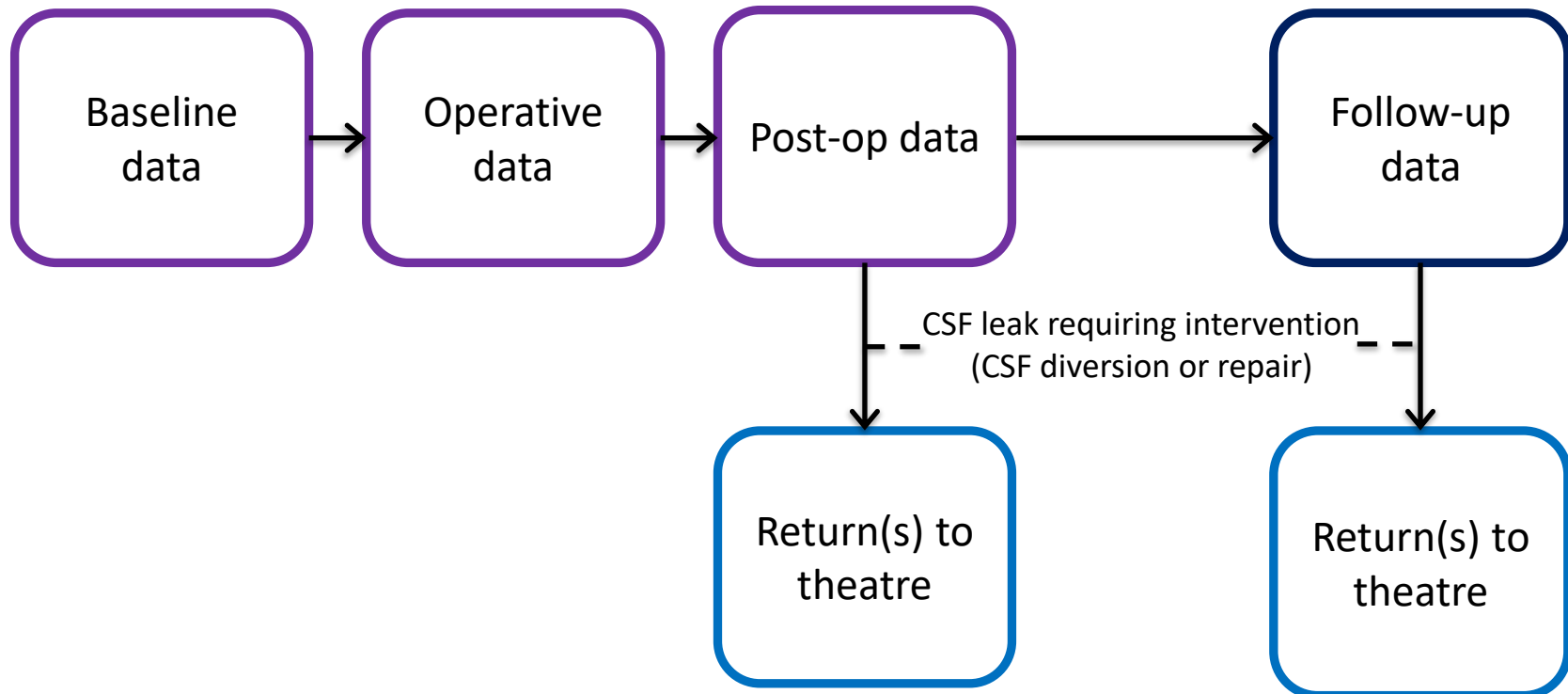
Case journeys

Index (primary) admission

Ideally data is collected whilst the patient is admitted or within 30 days of this.

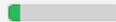
6-month follow-up

(clinic visits, readmissions)



Fill in the survey – The FAQ document contains useful tips if you need them

☰ Record ID: 000006 ◦ Not Live

Record: 000006
Progress:  11%

In Progress

CRANIAL

In Progress
Baseline

Not Started
Operative

Not Started
Post-operative

Not Started
6 Month Follow Up

Not Started
Confirmation

CRANIAL 1. Baseline

Welcome to the CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base - A National Prospective Service Evaluation on Incidence and Management (CRANIAL) project

Please find below our data collection proformas which should be filled in **within 30 days of admission**.

Please read our **Local Lead Guidance** and **Step-by-Step Guidance** documents before beginning. A **FAQ** document is available to answer the most common questions we encounter.

By collecting data, you are **offered citation as a CRANIAL Consortium collaborator** on the project report/manuscript(s). At the end of the data collection window, members of the local team are invited to apply for the **opportunity to be a full author**. Applications will be reviewed in the context of the performance of the local data team. Emphasis will be placed on **data completeness, with data quantity a secondary consideration at most (relative to the caseload of the respective local centre)**. Successful applicants will be invited to contribute significantly to the final audit report/manuscript after which, they will be entitled full authorship.

If you have any outstanding questions, feel free to contact us by emailing cranialnansig@gmail.com

Thank you and welcome to the CRANIAL team.

- 1.2 Age at primary surgery?
- 1.3 Biological sex? Male Female
- 1.4 Visual loss at presentation? Yes No
- 1.4.1 Is the patient blind (binocular and < 6/60)? Yes No

Record completion status

The form is interactive and loads different questions depending on your answers. Here, for example, question 1.4.1 only loads if your answer to 1.4 is "Yes"

NB: Data points which must be confirmed with the operating surgeons

- Maximum diameter of dural defect?
- Intra-op CSF leak (and grade)?
- Post-op CSF leak and confirmation method?
- Details of intra or post -operative method of CSF leak repair/prevention used (CSF diversion or direct skull base repair)
 - Method of CSF diversion used and for how long?
 - Was dura closed directly?
 - Flap used in repair?
 - Please select which types of grafts were used in the skull base repair?
 - Buttress used in skull base repair?
 - Tissue glue used in skull base repair?
 - Use of nasal pack?

NB: Post-op CSF leak interventions

- If a case requires re-intervention (CSF diversion and/or direct operative repair) for management of post-op CSF leak, then you will need to add an additional Report for this record.
- This is done via the 'Report a return to theatre' link (question 3.4.3.1 in the next slide).
- This is in addition to the standard 5 forms for this patient (Baseline, Operative, Post-operative, 6 month follow up and Confirmation).
- If the patient has multiple readmissions/reinterventions for post-op CSF leak management, you can add multiple "return to theatre" reports.
- Please discuss with the rest of the local team and ask for senior support if you need it.

3.4.3.1: Report a Return to Theatre

Record ID: 000006 ◦ Not Live

Record: 000006
Progress: 77%

- In Progress
- CRANIAL
- Completed
Baseline
- Completed
Operative
- Completed
Post-operative
- Not Started
6 Month Follow Up
- Not Started
Confirmation

CRANIAL 3. Post-operative

- 3.1 Length of hospital stay after primary surgery? (in days)
- 3.2 Post-operative conservative measure(s) utilised to prevent/ treat CSF leak?

 - Bed rest with head of the bed flat
 - Bed rest with head of the bed elevated
 - Advice to avoid heavy stress
 - Other
 - None recorded
- 3.3 Post-operative medical measure(s) utilised to prevent/ treat CSF leak?

 - Stool softeners
 - Prophylactic antibiotics
 - Acetazolamide
 - Other
 - None recorded
- 3.4 Did post-operative CSF rhinorrhoea occur during the index admission?

Yes No
- 3.4.1 After how many days post-op was the CSF rhinorrhea reported?
- 3.4.2 How was the post-operative CSF rhinorrhea confirmed?

 - Clinical assessment alone
 - Beta-2-transferrin
 - Significant pneumocephalus on CT Head
 - Other
 - Data not available
- 3.4.3 Did any episode of post-operative CSF rhinorrhoea require CSF diversion and/or operative repair (i.e. an intervention)?

Yes No

3.4.3.1

Report a return to theatre

If your answer to 3.4 is "No" then this concludes the "Post-operative" form and there is no need to Report a return to theatre

Similarly, you will only need to "Report a return to theatre" if your answer to 3.4.3 is "Yes"

Create a Return to Theatre Report

Add a report to record 000006 ✕

Report: Return to Theatre ▼

Custom name: Return to Theatre - 03-11-2019 12:31:18

Attach to: Phase 1. CRANIAL ▼

Create **Cancel**

We recommend naming the Report the date and time of when the Return to theatre occurred

Fill in the Return to Theatre Report

Record ID: 000006 Not Live

Record: 000006

Progress:  77%

Not Started

Return to Theatre - 03-11-2019 12:31:18

Not Started

Return to Theatre

All reports +

Report -

Return to Theatre

Please only fill out this form if:

1. You have already filled out the standard forms for this patient (baseline, operative, post-operative)

AND

2. The case requires **re-intervention (CSF diversion and/or direct operative repair)** for management of **post-operative CSF leak**.

We acknowledge that some CSF diversion interventions may not necessarily be performed in theatres in some units. The inclusion of these cases via this form is still valid regardless of whether the intervention was performed in theatre or not.

The questions below refer to the interventions used to treat post-operative CSF rhinorrhoea.

This form can be filled out multiple times, for each episode of CSF rhinorrhea requiring intervention.

1 How many days after the post-operative CSF rhinorrhea was confirmed, did the intervention take place?



2 Date of surgery

 (dd-mm-yyyy)

3 Please denote whether this is the patient's first (1), second (2), third (3), etc. return to theatre for post-operative



Close report

All reports

Add another

You can also use this screen to add further Return to Theatre Reports if needed

3-6 Month follow up

CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base

Search: in **Record** Exact n

View mode:

Progress by steps

Filter by record status:

- Completed records
- Incomplete records
- Not started
- Archived records

Filter by institute:

- All institutes

Record	1	2	3	4	5
000004 Test Institute	■	■	■	■	■
000005 Test Institute	■	■	■	■	■
000006 Test Institute	■	■	■	■	■

To fill in follow up details, select the "Records" tab to open a summary of all of your cases. Then double click on box 4 to fill in the 6 month follow up form - always ensure that you have the right Record ID (000006 in our case)

The Record is complete once all 5 boxes are green – there is no “submit” button

- Structure
- Forms
- Records
- Reports
- Surveys
- Monitoring
- Statistics
- Audit Trail
- Users
- Settings

CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base

Search:

in

Record

Exact match

View mode:

Progress by steps

Filter by record status:

- Completed records
- Incomplete records
- Not started
- Archived records

Filter by institute:

- All institutes

Record	1	2	3	4	5
000004 Test Institute					
000005 Test Institute					
000006 Test Institute					

Data submission and confidentiality

- Submit your data via computer.
- Each patient will get a unique anonymised Castor Record ID as shown above (000006 in this example case).
- As the Record ID is the only way to identify patients within Castor, it is important that you make a physical/excel list of patient NHS numbers and their corresponding Castor IDs.
- This 'coded identifier sheet' should be kept **secure** and on-site and will only be consulted if there is a query regarding a particular patient ID, or to re-open a record at a later date to enter follow up data.
- When data analysis is complete, your local team will receive instructions to destroy this sheet, thereby ensuring patient confidentiality, as all remaining data will be anonymised.

Further advice

- Please feel free to email us at:
cranialnansig@gmail.com
- Please visit our website at:
<https://nansig.org/cranial>
 - Here lies all the necessary project documents: Protocol, FAQ doc, Local Lead Guidance, Data Collection Checklist, etc.

