

# Launching NoMask Studie

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# The 'Who'

## **Sponsor**

Prof, M.D, Matthias Guckenberger  
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## **Principal Investigator**

Prof, M.D, Balermipas Panagiotis  
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## **Investigators (Physicist)**

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## **Investigators (RTTs) :**

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# University Hospital of Zürich «NoMask» Study

Recruiting Studies

**USZ** Universitäts  
Spital Zürich

Klinik für Radio-Onkologie

## NoMask

Randomized controlled trial comparing closed face masks vs surface guided radiation therapy for head and neck radiotherapy

HumRes66751 | SNCTP000006366 | BASEC2025-D0007 | NCT06870799



### Randomized Controlled Trial Comparing Closed Face Masks with Surface-Guided Radiation Therapy for Head and Neck Radiation Therapy

The study aims to investigate whether patient comfort and satisfaction can be improved with surface-guided radiation using an infrared light system. The mask commonly used in head and neck radiation will be omitted. The goal is to find an alternative to masks in radiation therapy, which is particularly relevant for patients with claustrophobia or other anxieties that may prevent them from receiving necessar...

**Recruitment status:** ● recruitment not started yet    **Disease category:** Head and Neck Cancer

**Trial sites:** Zurich

# University Hospital of Zürich «NoMask» Study

**USZ** Universitäts  
Spital Zürich  
University Hospital Zurich  
Department of Radiation Oncology

- Objectives
- Endpoints
- Study Design / Schedule
- Inclusion/Exclusion Criteria
- Procedures / Assessments
- Number of Participants (25)
- Study Duration (28 months)
- Statistical Considerations

## CLINICAL STUDY PROTOCOL

Randomized controlled trial comparing closed face masks vs surface guided radiation therapy for head and neck radiotherapy (NoMask Study)

|                           |  |
|---------------------------|--|
| Study type                | Clinical trial with authorized medical device  |
| Categorization            | Risk category A1 according to Art 6 ClinO-MD   |
| Study registration        | Clinicaltrials.gov NCT06870799   |
| Identifier                | NoMask Study   |
| Sponsor-investigator      | Professor Dr. Matthias Guckenberger<br>Department of Radiation Oncology<br>University Hospital Zürich<br>Rämistrasse 100<br>CH-8091 Zürich<br>Switzerland<br>matthias.guckenberger@usz.ch<br>Phone: +41 44 255 29 30<br>Fax: +41 44 255 45 47  |
| Principal Investigator    | Prof. Dr. med. Panagiotis Balempas<br>Department of Radiation Oncology<br>University Hospital Zürich<br>Rämistrasse 100<br>CH-8091 Zürich<br>Switzerland<br><a href="mailto:Panagiotis.balempas@usz.ch">Panagiotis.balempas@usz.ch</a><br>Phone: +41 44 255 42 04<br>+ 41 43 253 86 31 |
| Medical Device            | Control:<br>CIVCO Radiotherapy<br>Head Neck & Shoulder Mask<br><br>Intervention:<br>VisionRT<br>AlignRT Surface Guided Radiation Therapy (SGRT) Device   |
| Protocol version and Date | Version 1.6 18/03/2025   |

# The 'Why'



- **Standard of Care for Head & Neck Radiotherapy =** Immobilization with a closed-face thermoplastic mask
  - Pros: Non-Invasive, easy to fabricate, stable, accuracy
  - Cons: Comfort? Anxiety? Claustrophobia?
- **Setup Alternative:** Immobilization with an open-face thermoplastic mask comparable to closed-face masks
- **No Mask + SGRT?**
  - Improve comfort?
  - Reduce anxiety/claustrophobia?
  - Reduce materials and time?
  - Reduced skin dose from a mask?
  - New standard for palliation?



# The 'How'

## Timeline

Study Approval  
15.4.2025

Study Open  
13.5.2025

1. Patient Enrolled  
14.5.2025



# To B or not to B

**AB= Start with Mask**

**BA= Start without Mask**



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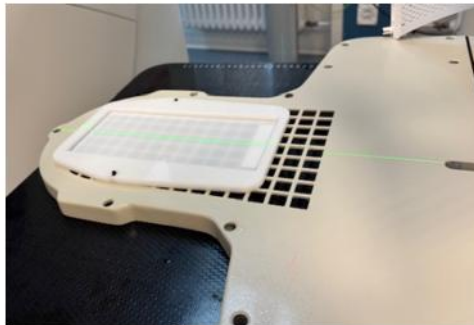
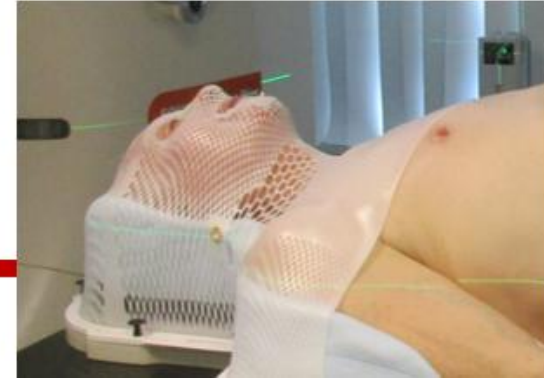
# The 'How'

*Between Approval and Recruitment*

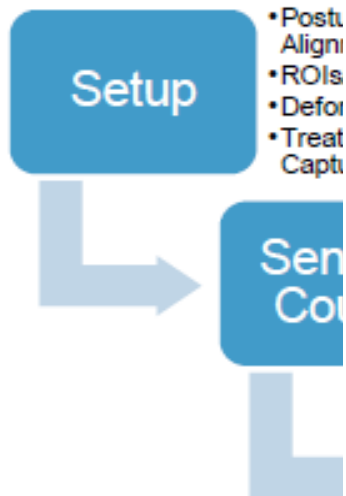
## Finalizing Setup



+



# The 'How'



**Wichtige Info für die Bestrahlung:**

**NoMask Study mit Maske vs. ohne Maske + SGRT**

**STUDY ARM (A/B)**

- **Arm AB:** beginnt RT **MIT** Maske, wechselt in der zweite Hälfte **OHNE** Maske
- **Arm BA:** beginnt RT **OHNE** Maske, wechselt in der zweite Hälfte **MIT** Maske
- Die Fraktionierung wird pro Patient unterschiedlich sein → das Datum der Lagerung wechseln auch anders (z.B bei 35Fx am Tag 18, bei 20 Fx am Tag 10) zählen + notieren

**OHNE MASKE SETUP**

- Ablauf: **1. Postural Alignment 2. ROI/Deltas (Send to Couch) 3. Deformation**
- Send to Couch und Reference Capture VOR CBCT
- CBCT → Match + Shift
- Zurück zur **CT Surface** + Gated Capture nehmen (Punkt aufs Jugulum setzten)
- Beam Hold Delay: 1 Sek erlaubt falls nötig

**TROUBLESHOOTING**

- **AlignRT Toleranzen: 2mm / 2°** → Während RT ausserhalb Toleranz? Neues CBCT fahren
- **AlignRT Breakdown?** «Off Protocol» MIT der Maske bestrahlen (max. 5 Sitzungen insgesamt, sonst fällt der Patient aus)

**IMAGING**

- Post-CBCT: erste 3 RT Sitzungen jeder Arm (A UND B) und dann 1x/Woche
- «Auto-Match» und immer speichern!

**FRAGEBOGEN**

- Komfort Fragebogen: Tag 1, dann 1x/Woche
- Präferenz Fragebogen am letzten Tag

|           |                                  |  |                               |
|-----------|----------------------------------|--|-------------------------------|
| Imaging   | Imaging Protokoll:               | Pre-CBCT: Tgl<br>Post-CBCT: Tag 1-3, dann 1x/Woche PRO Arm |                               |
|           | Randomization Arm (AB oder BA)   |  |                               |
|           | Datum der Lagerung WECHSEL       |  |                               |
|           | Matchen auf:                     |  |                               |
|           | Weitere Informationen zum Match: |  |                               |
|           | Gating:                          | <input type="checkbox"/> Ja                                | <input type="checkbox"/> Nein |
| Post CBCT | <input type="checkbox"/> Ja      | <input type="checkbox"/> Nein                              |                               |

Ist der Pat. währ ausserhalb Toleranz?  
\*\*Erneutes CBC

|   | Datum | Pre CBCT | Post CBCT | Bemerkungen | Komfort Fragebogen (1x/Woche) | Präferenz Fragebogen (Letzter RT) | Visum MTRA |
|---|-------|----------|-----------|-------------|-------------------------------|-----------------------------------|------------|
| 1 |       |          | X         |             | X                             |                                   |            |
| 2 |       |          | X         |             |                               |                                   |            |
| 3 |       |          | X         |             |                               |                                   |            |
| 4 |       |          |           |             |                               |                                   |            |
| 5 |       |          |           |             |                               |                                   |            |
| 6 |       |          |           |             | X                             |                                   |            |

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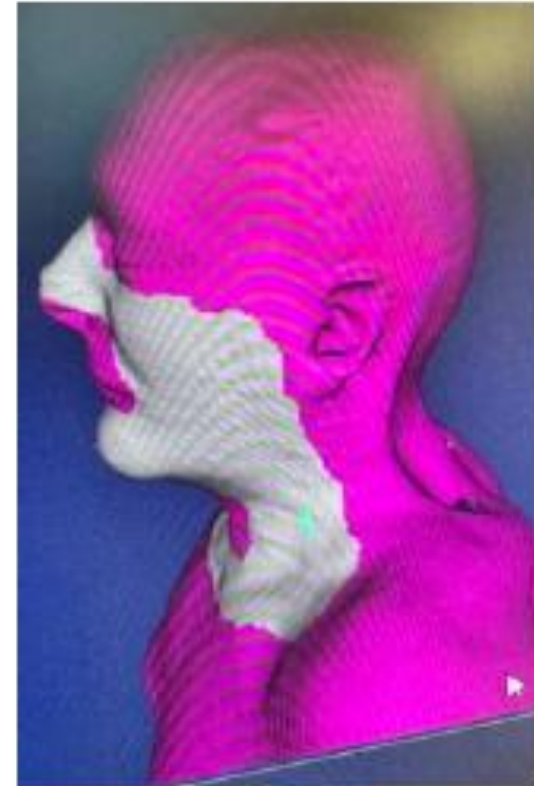
at

• 1 Sec Beam Hold Delay erlaubt

Post CBCT (Day 1-3, 1x/Week)

## The 'How'

ROI is the **virtual Mask**- Do all masks have the same exactly shape?



## Case Report Form (CRF)

### Kisim Textbausteine (signed electronically):

#### Eligibility:

| Inclusion criteria   | Yes | No |
|--|-----|----|
| Signed informed consent  |     |    |
| Indication for head and neck radiotherapy irrespective of tumor type                                 |     |    |
| Age ≥ 18 years   |     |    |
| Karnofsky performance status ≥ 70  |     |    |
| Willingness and ability to comply with schedule, treatment and other trial procedures                |     |    |
|  |     |    |
| Exclusion criteria   | Yes | No |
| Previous head and neck radiotherapy  |     |    |
| Pregnancy / ongoing breastfeeding  |     |    |
| Intention to become pregnant during course of trial  |     |    |
| Lack of safe contraception   |     |    |
| Known suspected non-compliance, drug or alcohol abuse  |     |    |
| Inability to follow study procedures, e.g. due to language problems                                  |     |    |
| Relation to investigator (family or professional)  |     |    |
| One of the following Tumour Types: Nasopharynx, Sinusnasal or CTV 5mm within the eyes or spinal cord |     |    |
|  |     |    |

*If all inclusion criteria = yes and all exclusion criteria = no, the patient is eligible.*

#### Baseline:

| General / Demographics                |  |
|---------------------------------------|--|
| Age at inclusion                      | years  |
| Pregnancy test (female patients only) | Date:<br><input type="checkbox"/> negative <input type="checkbox"/> positive <input type="checkbox"/> not applicable |
| Karnofsky performance status          | %  |

#### Note on Randomization:

|                           |                          |
|---------------------------|--------------------------|
| Randomization             | A: with mask, B: no mask |
| Allocation Arm (AB or BA) |                          |

## Patient Information/Consent

### PATIENTENINFORMATION ZUR TEILNAHME AN MEDIZINISCHER FORSCHUNG

Randomisierte kontrollierte Studie zum Vergleich von geschlossenen Gesichtsmasken mit oberflächengeführter Strahlentherapie für die Kopf- und Hals-Strahlentherapie (NoMask Study)

Randomized Controlled Trial comparing closed face masks vs Surface Guided Radiation Therapy for Head and Neck Radiotherapy (NoMask Study)

## Questionnaires

### Questionnaire on Overall Patient Comfort (Baseline at Simulation)

|   | 0 = None; 10 = Extreme |   |   |   |   |   |   |   |   |   |    |
|---|------------------------|---|---|---|---|---|---|---|---|---|----|
|   | 0                      | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| How much discomfort did you experience during simulation? |                        |   |   |   |   |   |   |   |   |   |    |
| How much anxiety did you experience during simulation?    |                        |   |   |   |   |   |   |   |   |   |    |
| How much pain did you experience during simulation?       |                        |   |   |   |   |   |   |   |   |   |    |

### Questionnaire on Overall Patient Comfort (First Day, then Weekly)

|  | 0 = None; 10 = Extreme |   |   |   |   |   |   |   |   |   |    |
|--|------------------------|---|---|---|---|---|---|---|---|---|----|
|  | 0                      | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| How much discomfort did you experience during treatment? |                        |   |   |   |   |   |   |   |   |   |    |
| How much anxiety did you experience during treatment?    |                        |   |   |   |   |   |   |   |   |   |    |
| How much pain did you experience during treatment?       |                        |   |   |   |   |   |   |   |   |   |    |

### Questionnaire on Overall Preference (Last Day)

|  | With Mask | No Mask |
|--|-----------|---------|
| Which position was overall more preferable for the radiotherapy treatment? |           |         |

# The 'How'

Documents

## Patient Database

| Patient ID (25) | Total Dose (Gy) | Total # of Fx | Randomisation | Fraction            | Pre CBCT Imaging (Inter-Fraction) |     |     |     |       |      | Additional CBCTs | Post CBCT Imaging (Intra Fraction) First 3, then 1x/Week |     |     |     |       |      |
|-----------------|-----------------|---------------|---------------|---------------------|-----------------------------------|-----|-----|-----|-------|------|------------------|--|-----|-----|-----|-------|------|
|                 |                 |               |               |                     | VRT                               | LNG | LAT | RTN | PITCH | ROLL | Number/Fx        | VRT  | LNG | LAT | RTN | PITCH | ROLL |
|                 | 68              | 34            | BA            | Simulation: CT ONLY | NA                                | NA  | NA  | NA  | NA    | NA   | NA               | NA   | NA  | NA  | NA  | NA    | NA   |
|                 |                 |               |               | 1                   |                                   |     |     |     |       |      | 1                |  |     |     |     |       |      |
|                 |                 |               |               | 2                   |                                   |     |     |     |       |      | 0                |  |     |     |     |       |      |
|                 |                 |               |               | 3                   |                                   |     |     |     |       |      | 0                |  |     |     |     |       |      |
|                 |                 |               |               | 4                   |                                   |     |     |     |       |      | 0                | NA   | NA  | NA  | NA  | NA    | NA   |
|                 |                 |               |               | 5                   |                                   |     |     |     |       |      | 0                | NA   | NA  | NA  | NA  | NA    | NA   |

| Weekly Questionnaire (1-10) |         |      | Final Questionnaire |              |
|-----------------------------|---------|------|---------------------|--------------|
| Comfort                     | Anxiety | Pain | With Mask           | Without Mask |
| 0                           | 0       | 0    | NA                  | NA           |
| 1                           | 0       | 0    | NA                  | NA           |
| NA                          | NA      | NA   | NA                  | NA           |
| NA                          | NA      | NA   | NA                  | NA           |
| NA                          | NA      | NA   | NA                  | NA           |
| NA                          | NA      | NA   | NA                  | NA           |

| Y                     | Z                   | AA                  | AB           | AC              | AD                      | AE       |
|-----------------------|---------------------|---------------------|--------------|-----------------|-------------------------|----------|
| Severe Adverse Events | Device Deficiencies | Concomitant Therapy | Demographics | Medical History | Time Required for Setup | COMMENTS |
|                       |                     |                     |              |                 |                         |          |
|                       |                     |                     |              |                 |                         |          |
|                       |                     |                     |              |                 |                         |          |

# Training and Competency

Post Ethics Approval (May 2025):

- **Study Kick Off Meeting**
  - Core Study Team (Doctors, Physics, RTTs)
  - Signed Delegation/Training Logs
- **USZ Clinical Research Meeting**
  - Presentation/Training for all doctors, physics and study office
- **Education/Training Session**
  - Specific training for all RTTs with focus on simulation, setup, treatment and workflow

**Ongoing:**

- **Good Clinical Practice (GCP) Course**  
→ **Core Study Team**

| Delegation and Authorization Log   |   |
|--|---|
| Project (Identifier and full title)  | Randomized controlled trial comparing closed face masks vs surface guided radiation therapy for head and neck radiotherapy (NoMask Study) |
| Sponsor (-Investigator):   | Prof. Matthias Guckenberger   |
| Principal Investigator:  | Prof. Panagiotis Balcermpas   |
| Authorization codes <small>(delegated sponsor responsibilities are marked in bold)</small> |   |
| Principal Investigator   | <input type="checkbox"/> ALL TASKS  |
| Investigator (Physician):  | <input type="checkbox"/> Obtain Informed Consent  |
|  | <input type="checkbox"/> Confirmation of eligibility  |
|  | <input type="checkbox"/> Clinical assessments and procedures, medical decisions   |
|  | <input type="checkbox"/> Safety assessments (AE, SAE etc.)  |
| Investigator (Radiation Therapist)   | <input type="checkbox"/> Ordering laboratory tests  |
|  | <input type="checkbox"/> Radiotherapy administration  |
|  | <input type="checkbox"/> Fabrication of immobilization mask and cushion   |
|  | <input type="checkbox"/> Acquisition of imaging   |
| Investigator (all)   | <input type="checkbox"/> Recording of radiotherapy compliance   |
|  | <input type="checkbox"/> Data extraction/collection for analysis  |
|  | <input type="checkbox"/> Study visit documentation  |
| CRC:   | <input type="checkbox"/> Activities related to Regulatory Submission  |
|  | <input type="checkbox"/> ISF maintenance, management of study documents   |
|  | <input type="checkbox"/> Randomization of patients  |
| Investigator (all) / CRC:  | <input type="checkbox"/> Visit planning according to study schedule   |
|  | <input type="checkbox"/> AE/SAE reporting   |
|  | <input type="checkbox"/> Handing out questionnaires   |
| Investigator / med. physicist:   | <input type="checkbox"/> Activities related to RT planning and RT-Plan adaptation   |
|  | <input type="checkbox"/> Data Analysis  |

| Study personnel training Record     |   |
|-------------------------------------|---|
| Project (Identifier and full title) | Randomized controlled trial comparing closed face masks vs surface guided radiation therapy for head and neck radiotherapy (NoMask Study)                                     |
| Sponsor:                            | Prof. Matthias Guckenberger   |
| Principal Investigator (PI):        | Prof. Panagiotis Balcermpas   |
| Date of Training:                   | 12.05.2025  |
| Training Details:                   | <ul style="list-style-type: none"> <li>• Informed Consent Form v2.0, 18.03.2025</li> <li>• Protocol v1.6, 18.03.2025</li> <li>• Textbausteine/CRF v1.0, 31.10.2024</li> </ul> |

# Post Launch

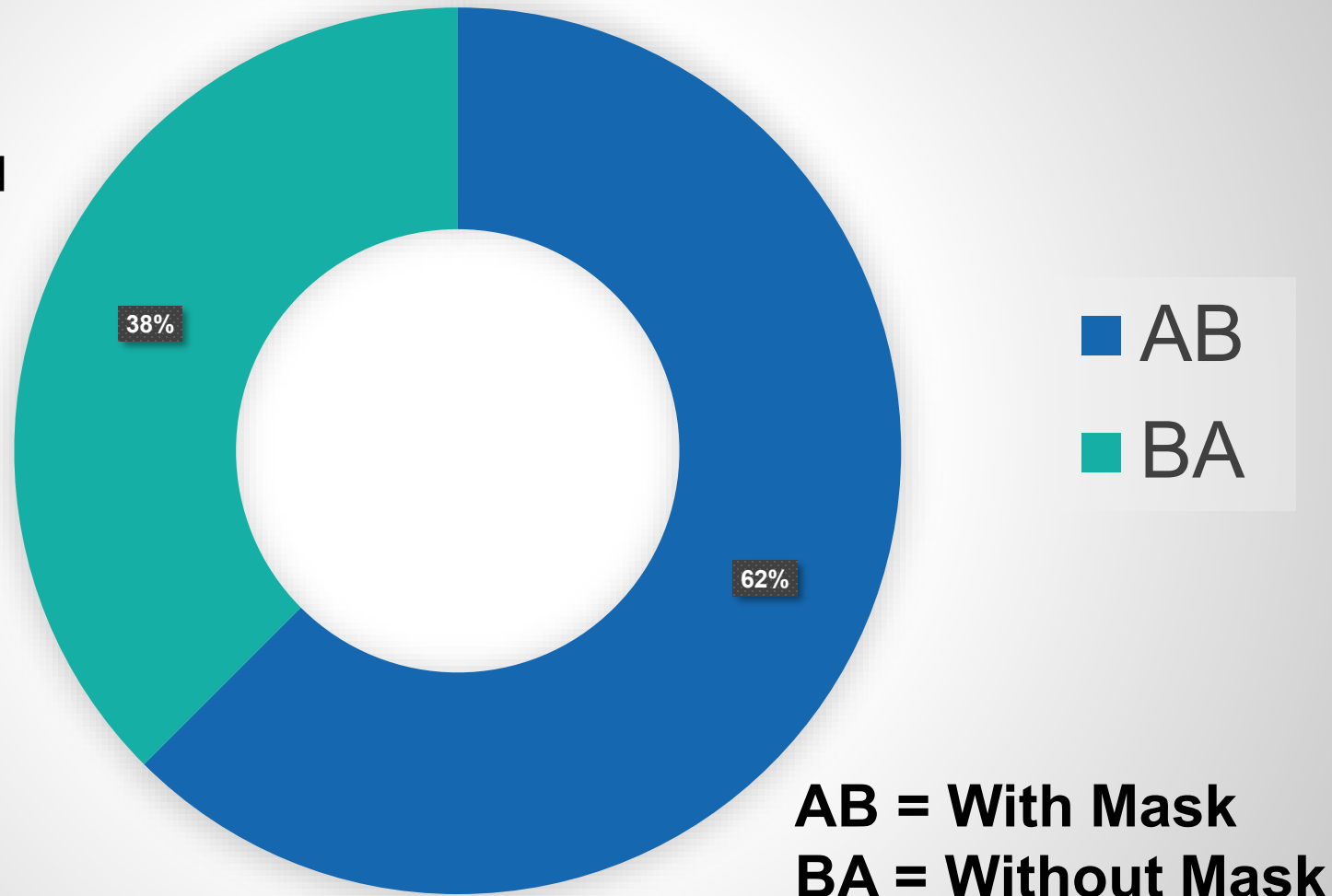
## Randomization

**As of 27.2.2026:**

16 patients enrolled

12 patients completed  
RT

4 currently under RT



# Continuous Improvement

## Staff Feedback

### With Mask

#### **Pros:**

- Setup = Quick

#### **Cons:**

- Swelling/Skin Reactions = Mask not fully closed

### Without Mask

#### **Pros:**

- Bolus directly on skin = Eliminate air gaps
- Detect swelling with SGRT
- Keeping similar staff = equivalent setup times

#### **Cons:**

- Monitor the patient and SGRT more closely
- Swallowing, breathing, sleeping impacts motion

# Continuous Improvement

## Staff Feedback

### With Mask

#### **Pros:**

- Setup = Quick

#### **Cons:**

- Swelling/Skin Reactions = Mask not fully closed

***Regular discussions & exchange  
amongst core study team***

### Without

#### **Pros**

- Bolus directly on skin = Eliminate air gaps
- Detect swelling with SGRT
- Keeping similar staff = equivalent setup times

#### **Cons:**

- Monitor the patient and SGRT more closely
- Swallowing, breathing, sleeping impacts motion

# Continuous Improvement

## Patient Feedback

**Darf ich euch keine mitteilen...**

## Key Takeaways / Lessons

*“It takes a village...”*

### Considerations:

- Patient Selection → Compliant
- Precise Simulations → Easier / Quicker Setups
- Adhering to clinic-specific protocols and workflows → ex. New Mask System, MR Only Workflows
- Adaptability → Treatment vs. Gated Capture, “one size fits all” ROI
- SGRT User Variability → Deltas, Deformation, Postural Alignment

**USZ** Universitäts  
Spital Zürich

**Thank you  
for your attention**

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