USZ Universitäts Spital Zürich

Optimizing SGRT Launching Maskless Treatments

Crystal Sulaiman, RTT

SGRT Europe 2025, 27.11.2025, London

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

1 Comfort & Preference

2 Accuracy

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

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HumRes Humanforschung Schweiz Recherche sur l'être humain en Suisse Ricerca umana in Svizzera Human Research Switzerland

NIH National Library of Medicine National Center for Biotechnology Information

ClinicalTrials.gov

swissmedic

Kanton Zürich Kantonale Ethikkommission

Agenda

1. The Who, Why, How
2. Training and Competency
3. Continuous Improvement
4. Key Takeaways / Lessons

The ‘Who’

Sponsor
Prof, M.D, Matthias Guckenberger
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Principial Investigator
Prof, M.D, Balermpas Panagiotis
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Radiation Oncology Study Office
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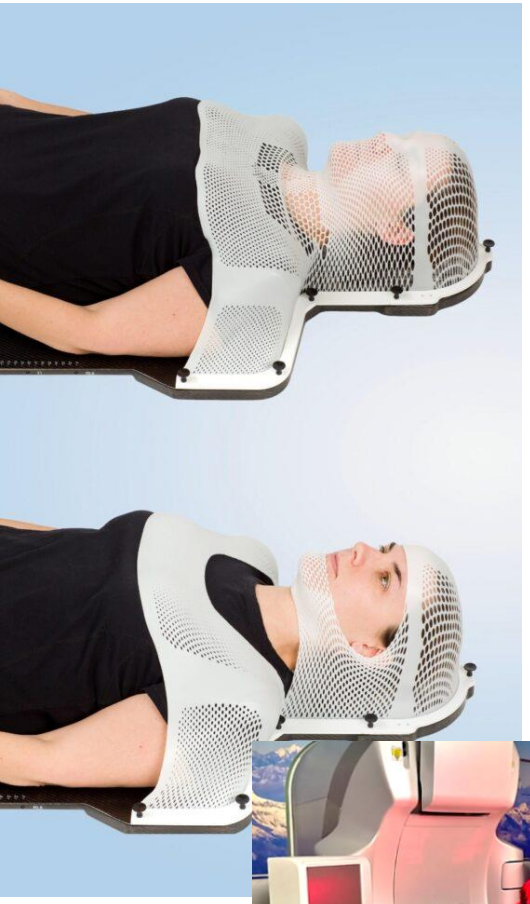
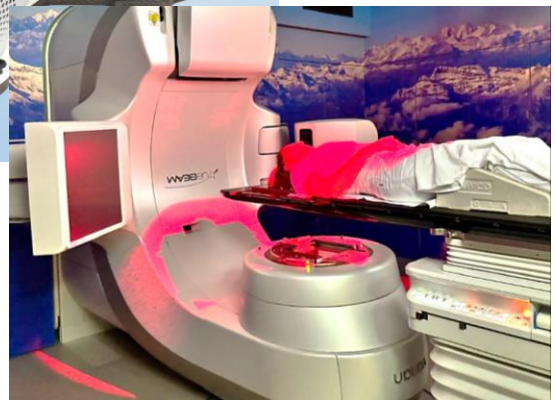
The ‘Why’





- **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?

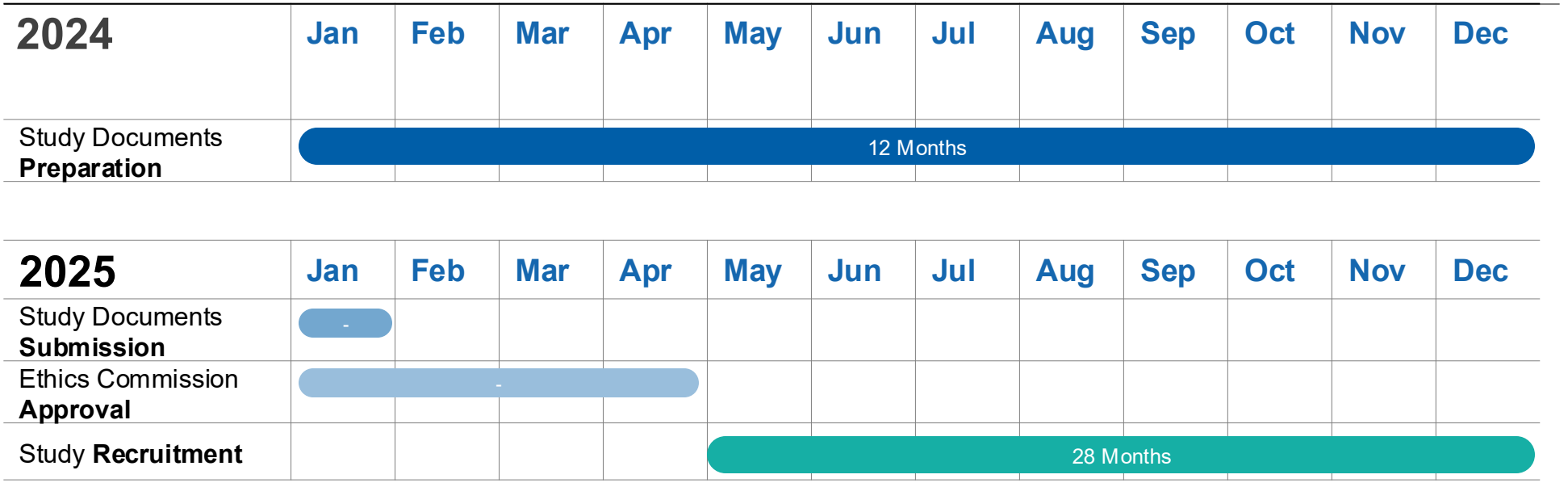
- **Setup Alternative:** Immobilization with an open-face thermoplastic mask comparable to closed-face masks

- **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	Study Open	1. Patient Enrolled
15.4.2025	13.5.2025	14.5.2025



The 'How'
Documents

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

USZ Universitäts Spital Zürich
University Hospital Zurich
Department of Radiation Oncology

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 Department of Radiation Oncology University Hospital Zürich Rämistrasse 100 CH-8091 Zürich Switzerland matthias.guckenberger@usz.ch Phone: +41 44 255 29 30 Fax: +41 44 255 45 47
Principal Investigator	Prof. Dr. med. Panagiotis Balermpas Department of Radiation Oncology University Hospital Zürich Rämistrasse 100 CH-8091 Zürich Switzerland Panagiotis.balermpas@usz.ch Phone: +41 44 255 42 04 + 41 43 253 86 31
Medical Device	**Control:** CIVCO Radiotherapy Head Neck & Shoulder Mask **Intervention:** VisionRT AlignRT Surface Guided Radiation Therapy (SGRT) Device
Protocol version and Date	Version 1.6 18/03/2025

The 'How'
Documents

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, Sinunasal 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: ☐ negative ☐ positive ☐ 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?		

Keane, M. et al. (2024). *Radiotherapy and Oncology*, *190*, 35-42.

The ‘How’
Documents

Patient Database

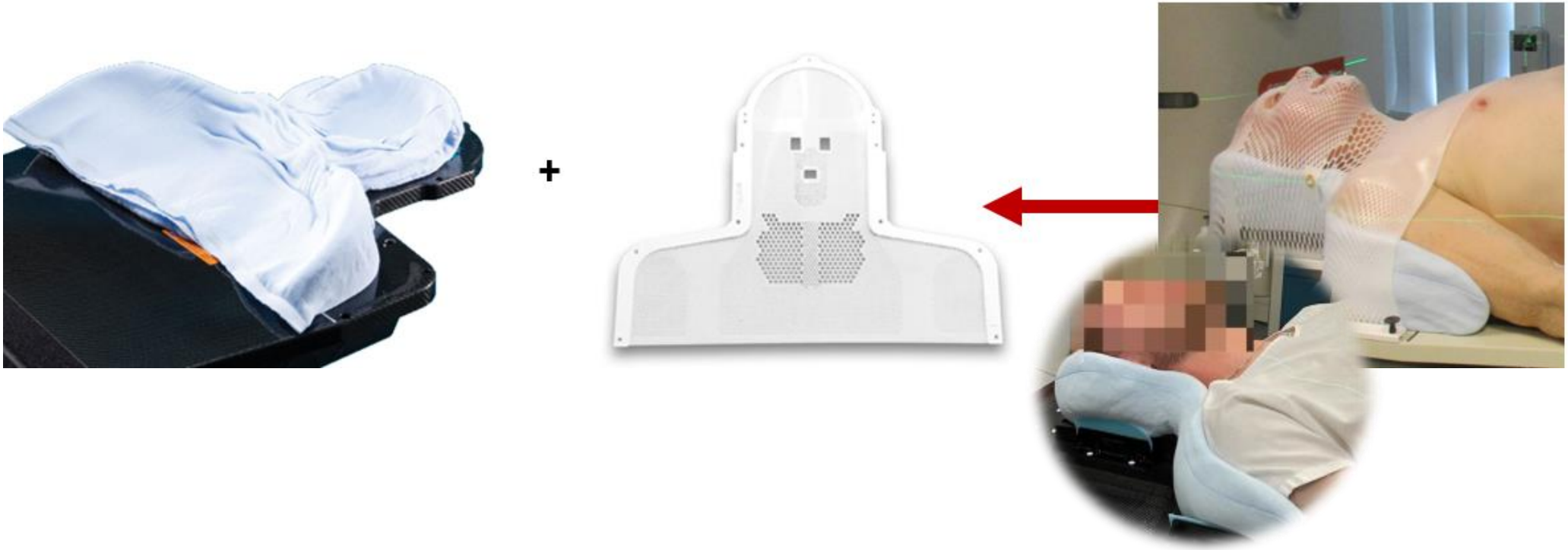
					Pre CBCT Imaging (Inter-Fraction)						Additional CBCTs	Post CBCT Imaging (Intra Fraction) First 3, then 1x/Week					
Patient ID (25)	Total Dose (Gy)	Total # of Fx	Randomisation	Fraction	VRT	LNG	LAT	RTN	PITCH	ROLL	Number/Fx	VRT	LNG	LAT	RTN	PITCH	ROLL
	68	34	BA	Simulation: CT ONLY	NA	NA	NA	NA	NA	NA	NA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

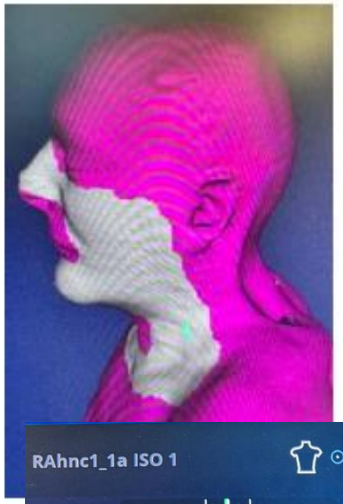
The ‘How’
Between Approval and Recruitment

Finalizing Setup

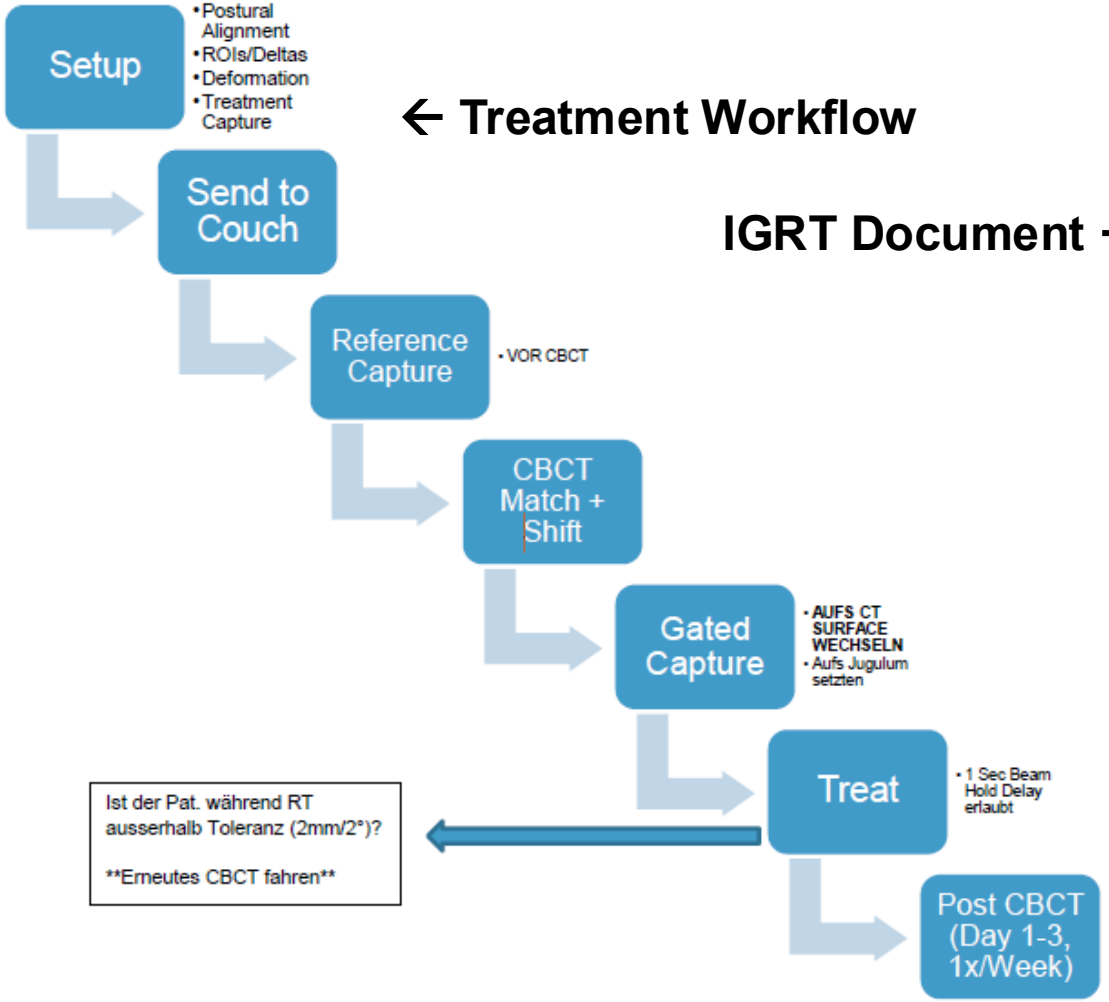


The ‘How’
Between Approval and Recruitment

Testing ROIs



The ‘How’
Between Approval and Recruitment



← Treatment Workflow

IGRT Document →

Allgemein

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 Protokol:	Pre-CBCT: Tgl 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:	☐ Ja	☐ Nein
Post CBCT	☐ Ja	☐ Nein

	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		

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

<u>Ongoing:</u>

- USZ 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 Balermpas

Authorization codes		*(delegated sponsor responsibilities are marked in bold)*
Principal Investigator	☐	ALL TASKS
Investigator (Physician):	☐	Obtain Informed Consent
	☐	Confirmation of eligibility
	☐	Clinical assessments and procedures, medical decisions
	☐	**Safety assessments (AE, SAE etc.)**
	☐	Ordering laboratory tests
Investigator (Radiation Therapist)	☐	Radiotherapy administration
	☐	Fabrication of immobilization mask and cushion
	☐	Acquisition of imaging
	☐	Recording of radiotherapy compliance
	☐	Data extraction/collection for analysis
Investigator (all)	☐	Study visit documentation
CRC:	☐	**Activities related to Regulatory Submission**
	☐	ISF maintenance, management of study documents
	☐	Randomization of patients
Investigator (all) / CRC:	☐	Visit planning according to study schedule
	☐	**AE/SAE reporting**
	☐	Handing out questionnaires
Investigator / med. physicist:	☐	Activities related to RT planning and RT-Plan adaptation
	☐	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 Balermpas

Date of Training:	12.05.2025
Training Details:	• Informed Consent Form v2.0, 18.03.2025 • Protocol v1.6, 18.03.2025 • Textbausteine/CRF v1.0, 31.10.2024

Continuous Improvement

Staff Feedback

With Mask

+ Setup = Quick
- Swelling/Skin Reactions = Mask not fully closed

Without Mask

+ Bolus directly on skin = Eliminate air gaps
+ Detect swelling with SGRT
+ Keeping similar staff = Familiarity

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

As of 10.11.2025:

11 patients enrolled

8 patients completed RT

3 currently under RT

Regular discussions/exchange amongst core study team

Key Takeaways / Lessons

“It takes a village…”

Considerations:

- Patient Selection → Compliability
- 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

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Thank you for your attention

& alignrt®