

# SOP EMINENT-ICH 005: Outcome assessment via telephone interview

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## Anmerkung

Das vorliegende Dokument ist eine Kopie aus der Applikation «Orca». Das Original, respektive die aktuell gültige Version ist unter [orca.dkfbasel.ch](http://orca.dkfbasel.ch) verfügbar.

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## 1. Introduction

The aim of this work instruction is to provide a step-by-step work manual for the telephone modified Rankin score (mRS) assessment in the EMINENT-ICH study.

## 2. Scope

This work instruction applies for telephone mRS assessment for visits 5 and 6 during the course of the EMINENT-ICH study.

## 3. Terms and abbreviations

- mRS            modified Rankin score

## 4. Roles and responsibilities

- Investigator: Conducting phone interview; provide patient list blinded for allocation
- Study Nurse: Conducting phone interview
- Sponsor: provide patient list blinded for allocation

## 5. Process

### 5.1. Tools and equipment

- mRS telephone assessment flow-chart
- telephone
- contact list with blinded patient treatment allocation

### 5.2. Interview

The investigator/study nurse will use the patient list (blinded for allocation) and contact patients for their 3 and 6-month follow-up mRS assessment.

After reaching the patients or relatives in case the patient is not able to answer him/herself (mute/not capable), the investigator will introduce him/herself, say that he works for the EMINENT-ICH study and state the purpose for the telephone call, which is to assess the degree of disability in daily life through **3 simple yes/no questions**.

**Patients and/or their relatives must be informed to withhold their allocation status!**

Thereafter, question one will be asked:

#1: “ Could you live alone with any help from another person? This means being able to bathe, use the toilet, shop, prepare or get meals and manage finances.”

### **5.2.1. In case the first answer is “yes”**

If yes then the investigator follows up with: “Can you do everything that you were doing right before your haemorrhage, even if slower and not as much?”

If no, this equals to an mRS of 2. If yes, then the last question will be asked: “Are you back to the way you were right before your bleeding?”

If yes then this equals to an mRS of 0, if no this equals to an mRS of 1.

### **5.2.2. In case the first answer is “no”**

If the answer to the first question is “no”, the investigator will ask: “Can you walk from one room to another without help from another person?”

If yes, this equals to an mRS of 3, if no, the investigator will ask the last question: “Can you sit up on bed without any help?”

If the answer is yes, this equals to an mRS of 4, if no this equals to an mRS of 5.

### **5.2.3. In case the patient has died**

If the patient has died, this will be counted as an mRS of 6.

### **5.2.4. End of the phone call**

The investigator will thank the patient/relative for their time and cooperation and will end the phone call.

The investigator will provide the mRS value together with the patient ID and the visit number to the EMINENT-ICH core team (eminent-ich@usb.ch).

## 6. Process diagram

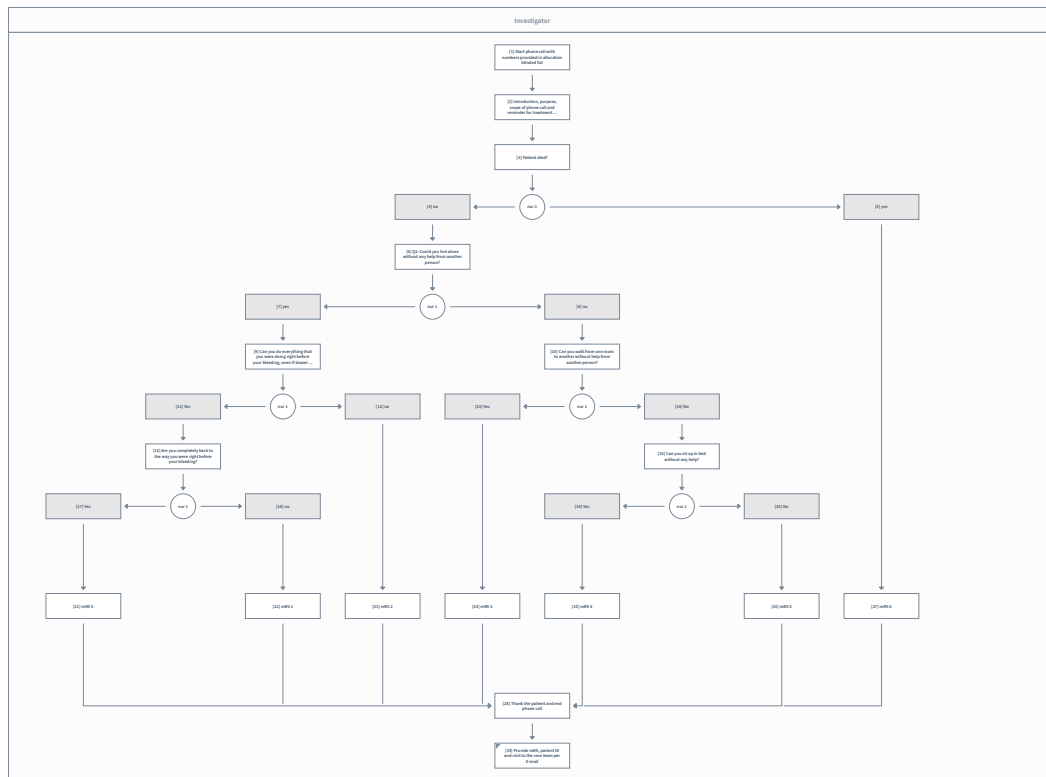


Diagramm 1

## 7. Measurables

mRS assessed for all patients

## 8. References

- Original publication ([bruno-et-al-2011-simplified-modified-rankin-scale-questionnaire.pdf<sup>1</sup>](#))

1. <https://orca.dkfbasel.ch/download/process/4b60b177-6f38-11ee-b913-0242ac120005>

## **9. Details zu Diagramm 1**

**[1] Start phone call with numbers provided in allocation blinded list**

**[2] Introduction, purpose, scope of phone call and reminder for treatment allocation blinding**

**[3] Patient died?**

**[4] no**

**[5] yes**

**[6] Q1: Could you live alone without any help from another person?**

**[7] yes**

**[8] no**

**[9] Can you do everything that you were doing right before your bleeding, even if slower and not so much?**

**[10] Can you walk from one room to another without help from another person?**

**[11] Yes**

**[12] no**

**[13] Yes**

**[14] No**

**[15] Are you completely back to the way you were right before your bleeding?**

**[16] Can you sit up in bed without any help?**

**[17] Yes**

**[18] no**

**[19] Yes**

**[20] No**

**[21] mRS 0**

**[22] mRS 1**

**[23] mRS 2**

**[24] mRS 3**

**[25] mRS 4**

**[26] mRS 5**

**[27] mRS 6**

**[28] Thank the patient and end phone call**

**[29] Provide mRS, patient ID and visit to the core team per E-mail**

## Änderungsverzeichnis

Version	Beschreibung
Version: 1.0.0 (aktuell)	13.03.2023: First draft of SOP