# Prospective multicentre study (RODEO) investigating dose reduction of tyrosine kinase inhibitors (TKIs) in chronic myeloid leukaemia (CML)

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## Introduction

- Dose reduction of TKIs:
  - ✓ Can reduce adverse events while maintaining effectiveness[1,2]
  - ✓ Can improve quality of life[3]
  - ✓ Is supported by patients and healthcare providers[4]
- Limitations:
  - One-size fits all approach
  - No patient involvement
- RODEO: **patient-guided dose reduction strategy**[5]

### OBJECTIVE

To describe the study population and evaluate the primary outcome of the RODEO study as of June 2024.

## Methods

Acces the study protocol here:

In short:

**Study design**

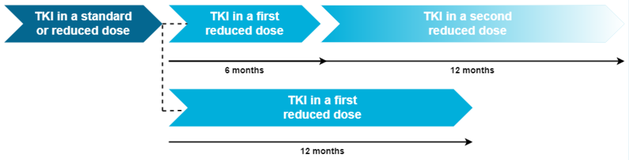
Prospective, multicenter & single-arm.

**Study population**

147 adult chronic phase CML patients in at least stable major molecular remission and treated with 1st or 2nd generation TKI. There were no restrictions on lower dosage use than standard.

**Intervention**

1. Patient decision aid https://www.keuzehulpcml.nl/
2. Shared-decision making consultation
3. Personalized reduced TKI dose




**Primary outcome**

Proportion of patients restarting their initial dose at 12 months follow-up.

**Secondary outcomes**

Validated PROMs:

- Side effects
- Quality of life
- Medication adherence & beliefs
- Healthcare consumption and productivity
- Distress and remorse

Shared-decision making quality

## Interim results

**Table 1**: Participant characteristics RODEO trial

| Participant characteristics | |
|---|---|
| **Participants** | 148 |
| Gender, male | 94 (63.5%) |
| Mean age (SD) | 59 (13.8) |
| Median disease duration, years (range) | 9.1 (1.6 - 27.2) |
| **Treatment at baseline**[a] | |
| Imatinib | 67 (45.3%) |
| 2nd generation TKI | 77 (52.0%) |
| **Molecular response at baseline**[b] | |
| Major molecular remission (MMR) | 12 (8.1%) |
| Deep molecular remission (DMR) | 136 (91.9%) |
| Median time in MMR or DMR, months (range) | 44 (7 - 226) |
| **Median dose reduction from initial dose (range)** | 30% (14 - 75%) |

[a] 5 missing values. [b] 1 missing value

In February 2024, the planned inclusion goal was achieved, resulting in the study population as depicted by Table 1.

As of June 2024, 97 participants had completed the 12-month follow-up.

Of these, 13.4% experienced treatment failure, requiring them to restart their initial dose, as shown in Table 2.

**Table 2:** Interim results at 12 months follow-up

| Interim results at 12 months follow-up (n=97) | |
|---|---|
| **Treatment failure** | **13 (13.4%)** |
| (expected) loss of MMR | 11 (11.3%) |
| Other | 2 (2.1%) |

The median time to regain MMR after a loss was 72 days, with a range of 41 to 287 days (n=6). As of 6 June, three participants were still working towards reaching MMR, and no follow-up was recorded for one participant.

## Conclusion

The patient-guided dose reduction strategy (RODEO) is safe for at least some patients with CML.

## References

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