# Treat-to-target in systemic lupus erythematosus: a pilot study

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON52205

**Source**
ToetsingOnline

**Brief title**
T2T-SLE

### Condition

- Autoimmune disorders

**Synonym**
Lupus, SLE

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Astra Zeneca,European Union□s Horizon 2020 research and innovation programme support for the Amsterdam Rheumatology Center for Autoimmune Diseases (ARCAID; grant number 847551)

## Intervention

**Keyword:** Rheumatology, Systemic Lupus Erythematosus, treat-to-target

## Outcome measures

### Primary outcome

A mixed methods approach will be adopted to establish usability, feasibility and acceptability. Data will be collected to assess the following primary endpoints:

• Usability: Adherence rates and System usability scale (SUS)

• Feasibility: Recruitment and retention rates, time required to recruit to target sample, number of eligible participants required to recruit required sample size, rate of completion of the intervention (i.e. number of participants who complete all aspects of the intervention)

• Acceptability: assess through qualitative and quantitative questionnaires.

### Secondary outcome

Although the pilot study is not powered to detect clinically significant changes in clinical outcome measures, we will collect these as secondary data in order to generate interval estimates of the change and to also determine whether the testing components that would be used in a larger evaluation are feasible.

- Changes in disease activity (reported by cSLEDAI-2k and PGA)

- Damage accrual at week 24 (SDI),

- HRQoL (SF-36)

- Proportion of disease flares apparition (SLEDAI-2K flare index)

These data could enable the statistical power calculations for a subsequent

larger scale evaluation to assess the effectiveness of the T2T intervention as

part of routine outpatient care.

# Study description

### Background summary

The treating-to-target (T2T) therapeutic strategy has been endorsed by experts in systemic lupus erythematosus (SLE) but thus far it has not been properly studied nor implemented. The field of health informatics has emerged as an interdisciplinary science that could represent a way to facilitative clinical decision support in the context of a T2T approach in SLE, providing a rapid tool of computerized guidelines for an adequate therapy adjustment in order to reach the treatment target efficiently. The computerized clinical decision support systems, or CDSS, are e-health information systems designed to assist clinicians and other health care professionals in clinical decision-making, and can improve adherence to clinical guidelines.

### Study objective

The primary objectives of the study are as follow:
1) To assess usability and adherence to a T2T strategy implemented through a digital e-health tool website (i.e. do physicians work through all aspects of the website and take part in all the T2T process: target selection and medication adjustments delivered by the e-health tool)
2) To assess acceptability of the T2T strategy implemented through a digital e-health tool for the management of SLE patients (i.e. do patients and physicians agree to the T2T approach and is it feasible to identify a treatment target for each patient)
3) To assess the feasibility of recruitment including length of time required to complete participant recruitment and retention rates (i.e. is it feasible to recruit the number of participants required within the specified recruitment time period, the proportion of patients that can/wishes to participate and the proportion of *drop outs*)
4) To conduct a qualitative and quantitative process evaluation with participants: patients and health care providers (HCP); to identify barriers and enabling factors for completion of the study and its potential reproducibility to larger T2T trials.

The secondary objectives are to estimate the variability in disease activity, SLICC damage index, health related quality of life (HRQoL) and proportion of

disease flares apparition, by generating interval estimates of the mean difference over time for each outcome measure. This will enable the statistical power calculations for a subsequent larger scale evaluation to assess the effectiveness of the T2T intervention as part of routine outpatient care.

### Study design

A 24-weeks, non-randomized, cluster, multicentre, treat-to-target pilot study.

### Intervention

Patients will be grouped per treatment centre (cluster), where two out of the four study centres will treat patients according to T2T, for which a target will be defined by integrating all important aspects of the disease - clinical state, measured by SLEDAI-2K and *clinical* SLEDAI-2K, Physician Global Assessment (PGA), and current medication - through an input into the e-Health tool, accompanied by the patient's wishes regarding her or his treatment. This will allow to then generate the output defined as recommendations for regular medication adjustments depending on the pre-defined target. This recommendations can be implemented accordingly by a rheumatologist and/or a nurse dedicated to SLE. In the two other centres, routine outpatient care will be performed and will be evaluated as a control group where patients will be treated following the regular standard of care according to the treating physician*s judgment and criteria.

### Study burden and risks

The burden associated with the study is minimal, and represented by extra visits to the outpatient clinic by the patients in the T2T arm for target achievement evaluation, plus extra physical examinations or other test as required. Patients and physicians will be also asked to complete several questionnaire before, during and near the end of the study on the acceptability of the overall T2T strategy implementation and the usability of the digital e-health tool for the management of SLE patients. There is no direct risk associated to the study since no investigational treatment product is involve. Patients have no direct benefit from participating in this study, since their regular clinical assessment and treatment is not dependent on their participation. Patients on the T2T arm will participate actively in the decision making process regarding the treatment strategy.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age 18 years or older
- Diagnosed with SLE according to the American College of Rheumatology (ACR) revised criteria for the classification of SLE.
- Signed informed consent form

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Life-threatening SLE manifestations that require intensive care treatment
- Pregnancy or breastfeeding during the time period of the pilot study

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

## Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 03-04-2023 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | SLE-T2T |
| Registration: | No |

# Ethics review

Approved WMO

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| Date: | 28-11-2022 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL78830.018.22 |