ISRCTN86354475 https://doi.org/10.1186/ISRCTN86354475

Survey on experiences with vitiligo treatment

Submission date
22/01/2025

Recruitment status
No longer recruiting

Registration date
10/02/2025

Overall study status
Completed

Last Edited
04/02/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Vitiligo is a common autoimmune skin condition that causes white patches and can significantly affect a person's quality of life. Treatment decisions for vitiligo vary depending on individual goals and circumstances, making it important for doctors and patients to work together to decide on the best approach. This study explores how patients feel about shared decision-making (SDM) when choosing their treatment and identifies any unmet needs they face during treatment. The study aims to understand how much patients feel involved in decision-making about their treatment. It will explore how factors like age, education, and ethnicity affect SDM and unmet needs, assess patients' uncertainty or conflict about decisions, and identify gaps in current vitiligo treatment.

Who can participate?
The study will include 100–150 patients per country who have a doctor-confirmed diagnosis of vitiligo, are 18 or older, and visited a dermatology department in the past two years.

What does the study involve?
A survey study will be conducted across three countries (Netherlands, Singapore, and Egypt) in collaboration with hospitals in these regions. The 10-minute survey asks about demographics, and unmet needs, and uses validated tools to measure SDM and decision-making challenges. The survey was developed and tested with input from vitiligo patients and translated into English and Arabic for use in all three countries.

What are the possible benefits and risks of participating?
This study aims to better understand how patients experience SDM and identify areas where vitiligo treatment can be improved. Insights will help improve patient-centred care for vitiligo globally. The study has a minimal burden for participants and has been cleared by the ethical committee.

Where is the study run from?
Amsterdam University Medical Centers, Netherlands

When is the study starting and how long is it expected to run for?
May 2024 to May 2025

Who is funding the study?
Amsterdam University Medical Centers, Netherlands

Who is the main contact?
Dr Marlide Jukema, m.jukema@amsterdamumc.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Albert Wolkerstorfer

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 020 566 9111
a.wolkerstorfer@amsterdamumc.nl

Additional identifiers

Study information

Scientific Title
Survey on experiences with vitiligo treatment

Study objectives
Vitiligo is a common autoimmune disorder characterised by depigmented macules which has a significant impact on patients' quality of life. Treatment options vary based on individual factors and goals, making shared decision-making (SDM) crucial for aligning treatment with patient preferences. This study aims to investigate how patients experience shared decision-making in choosing their vitiligo treatment and which unmet needs they encounter in the treatment of vitiligo.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/08/2024, The Medical Ethics Committee of the Amsterdam University Medical Centers (Meibergdreef 9, Amsterdam, 1105 AZ, Netherlands; +31 020 566 9111; metc@amsterdamumc.nl), ref: 2024.0692

Study design
Multinational cross-sectional exploratory survey study

Primary study design

Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Vitiligo

Interventions
This multinational, cross-sectional exploratory survey study will be conducted across three countries at the Amsterdam UMC, National University Singapore, Cairo University and Ain Shams University. The survey will be carried out using the free online survey tool 'LimeSurvey'.

The patients will be asked to fill out a questionnaire that will take about 10 minutes to complete. The questionnaire was developed with the input of three patients of the Dutch National Vitiligo Patient Association. It was also tested by three vitiligo patients who visited the dermatology department in Amsterdam UMC and was adjusted based on their feedback. The survey contains questions about demographic variables (such as educational level, ethnicity, etc.) and unmet needs during the treatment of vitiligo. Besides this, three validated questionnaires will be used: the 9-item Shared Decision-Making Questionnaire (SDM-Q-9) (Each item will be scored on a 6-point Likert scale ranging from 0 (no SDM) to 5 (optimal SDM). This results in a score ranging from 0 to 45, which will be converted to a scale of 0–100), the Control Preference Scale (CPS) and the Decisional Conflict Scale (DCS) for assessing the need for and extent of shared decision-making. The survey was translated into English and Arabic for the participating hospitals in Singapore and Egypt by a certified translation agency. The English survey and the Arabic survey will be reviewed in LimeSurvey by two doctors who are (near)-native speakers of these languages before sending the survey out to the patients.

Data Collection and Analysis: Patients will receive an email with a secure link to the survey. Data will be anonymized and hosted securely by the Amsterdam University Medical Centre. Statistical analysis will summarize patient experiences and examine differences across countries and between demographic groups.

Intervention Type
Other

Primary outcome(s)
The following primary outcome measures are assessed at one time point after treatment:
1. The extent to which shared decision-making (SDM) is experienced will be measured using the validated nine-item Shared Decision-Making Questionnaire (SDM-Q)
2. The extent to which patients want to be involved in the SDM process will be measured using the validated Control Preference Scale
3. The uncertainty patients experience when making healthcare decisions will be measured using the Decisional Conflict Scale
4. Potential shortcomings patients may encounter during their treatment for vitiligo measured using a 5-point Likert scale (ranging from strongly disagree to strongly agree)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date

31/05/2025

Eligibility

Key inclusion criteria
1. Physician-based diagnosis of non-segmental vitiligo
2. Aged 18 years or above
3. Had a treatment visit at the dermatology department in the past 2 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
Non segmental vitiligo

Date of first enrolment
26/11/2024

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
Egypt

Netherlands

Singapore

Study participating centre
Amsterdam UMC
Meibergdreef 9

Amsterdam
Netherlands
1105 AZ

Study participating centre
National University Singapore
Lower Kent Ridge RD 21
Singapore
Singapore
119077

Study participating centre
Cairo University
Gamaa Street 1
Giza
Egypt
12613

Study participating centre
Ain Shams University
El-Khalyfa El-Mamoun Street Abbasya
Cairo
Egypt
11566

Sponsor information

Organisation
Amsterdam University Medical Centers

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amsterdam University Medical Centers

Alternative Name(s)
Amsterdam UMC, Amsterdam University Medical Centres, AUMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Marlide Jukema, m.jukema@amsterdamumc.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 124	24/07/2024	24/01/2025	No	Yes
Protocol file			24/01/2025	No	No