ISRCTN24123156 https://doi.org/10.1186/ISRCTN24123156

A study of vitamin D added to standard treatment for people with alopecia areata

Submission date 05/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/08/2026	**Overall study status** Completed	
Last Edited 06/08/2026	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Vitamin D as an adjunct to janus kinase inhibitors for alopecia areata: a randomized controlled trial

Acronym
VIT-JAK-AA

Study objectives
To evaluate whether adjunctive vitamin D supplementation improves the efficacy of Janus kinase (JAK) inhibitor therapy in patients with alopecia areata by assessing hair regrowth, quality of life, safety, and serum vitamin D levels over a 12-month follow-up period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/12/2024, Institutional Review Board (IRB) committee in King Hussein Hospital, Jordanian Royal Medical Services (-, Amman, 56666, Jordan; +962 777797718; Mraghda656@gmail.com), ref: 1964 (approval no:18/2024)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Alopecia areata (including alopecia totalis and alopecia universalis)

Interventions
Participants are randomly allocated in a 1:1 ratio to one of two parallel treatment groups. Randomisation was performed using a computer-generated block randomisation sequence in a 1: 1 ratio. Allocation concealment was achieved through a centralised electronic randomisation system, preventing foreknowledge of group assignment prior to enrolment.

Intervention group: Janus kinase (JAK) inhibitor therapy plus oral vitamin D3 (cholecalciferol) supplementation administered according to the study protocol for 12 months.

Control group: Janus kinase (JAK) inhibitor therapy alone for 12 months, with identical clinical follow-up and assessments.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Baricitinib, tofacitinib, and cholecalciferol (vitamin D3)

Primary outcome(s)
1. Severity of alopecia measured using Severity of Alopecia Tool (SALT) at baseline, 6 months, and 12 months

Key secondary outcome(s)
1. Safety and treatment-related adverse events measured using clinical assessment, adverse event reporting, and laboratory monitoring (CBC, liver function tests, lipid profile, calcium, and serum vitamin D). at throughout the 12-month study period

2. Quality of life measured using Dermatology Life Quality Index (DLQI) at baseline, 6 months, and 12 months

3. Serum 25-hydroxyvitamin D level measured using nmol/L at baseline, 6 months, and 12 months

4. Treatment adherence measured using patient adherence assessed by treatment compliance and follow-up attendance at throughout the 12-month study period

Completion date
05/08/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Clinical diagnosis of alopecia areata, alopecia totalis, or alopecia universalis
3. No treatment with Janus kinase inhibitors during the previous 6 months
4. Able and willing to provide informed consent and comply with all study visits and procedures

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Active autoimmune disease contraindicating Janus kinase inhibitor therapy
3. Positive tuberculosis screening (Quantiferon)
4. Positive hepatitis screening
5. Abnormal baseline laboratory findings including LDL >150 mg/dL, triglycerides >200 mg/dL, total cholesterol >200 mg/dL, AST >37 U/L, or ALT >37 U/L
6. Hypercalcemia
7. Vitamin D toxicity
8. Recent malignancy
9. Active systemic infection
10. Current systemic immunosuppressive therapy
11. Known secondary vitamin D deficiency

Date of first enrolment
05/12/2024

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Jordan

Study participating centre
Royal Medical Services – King Hussein Medical Center
Amman
Amman
Jordan
66666

Sponsor information

Organisation
University of Jeddah

ROR
https://ror.org/015ya8798

Organisation
Jordanian Universities Network (Jordan)

ROR
https://ror.org/03ncj7n33

Funder(s)

Funder type

Funder Name
University of jeddah

Funder Name
King Hussein Cancer Center

Alternative Name(s)
Al-Hussein Cancer Center, The King Hussein Cancer Center, , KHCC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Jordan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	18/12/2024	06/08/2026	No	No