Protocol

Title

Real-world evidence of dupilumab efficacy and adverse events in atopic dermatitis

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Aim

The aim of this systematic review is to review the efficacy and adverse events of dupilumab in patients with atopic dermatitis based on real-world evidence.

Study design

A systematic review

Eligibility criteria

For studies to be included they must 1) include AD patients treated with dupilumab, 2) be an observational study, 3) include at least 10 AD patients, 4) present data on at least one of the following: mean percentage

reduction in Eczema Area and Severity Index (EASI) in AD patients from baseline until the evaluation of the efficacy; proportion of AD patients achieving EASI-50, 75, and 90; proportion of patients achieving an Investigator Global Assessment (IGA) of 0/1; mean percentage reduction in, respectively, Dermatology Life Quality Index (DLQI), Patient-Oriented Eczema Measure (POEM), Pruritus Numerical Rating Scale (P-NRS), Pruritus Visual Analogue Score (P-VAS), SCORing Atopic Dermatitis (SCORAD); drug survival; common adverse events (AE) reported after treatment with dupilumab (common AEs were defined as being reported in >1% of patients, in at least 3 studies), 5) be published in English.

Literature search

Two independent authors (A.H. and N.D.L.) will search and screen 2 medical databases (Pubmed and Embase) using the search term: 'dupilumab'. No search filters will be applied. Furthermore, reference lists of key articles and relevant reviews will be screened. All articles will be screened from inception of the databases until October 2019.

Selection of studies and data extraction

The literature search will be performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and full search process and reasons for exclusion of studies, will be outlined in a PRISMA flow diagram.

For all included publications we will retrieve data on:

1. Study details: authors, publication year, country.
2. Populations characteristics: age, gender, baseline data on severity of AD, and total number of participants.
3. Dupilumab: dosage, frequency, and concomitant therapy.
4. Efficacy of dupilumab: the mean percentage reduction in EASI from baseline until the evaluation of the efficacy, the proportion of AD patients achieving EASI-50, 75 and 90, mean percentage reduction in, respectively, DLQI, POEM, P-NRS, P-VAS, SCORAD, and the proportion of patients achieving an IGA of 0/1.
5. Drug survival of dupilumab: proportion of patients persistent on dupilumab and proportion of patients who discontinued dupilumab.
6. Safety of dupilumab: proportion of patients reporting common AEs.

Outcomes

Primary outcomes: the mean percentage reduction in EASI from baseline until the evaluation of the efficacy and the proportion of AD patients achieving EASI-50, 75 and 90.
Secondary outcomes: the mean percentage reduction in, respectively, DLQI, POEM, P-NRS, P-VAS, SCORAD, the proportion of patients achieving an IGA of 0/1, drug survival, and commonly reported AEs.

Data synthesis

Means of efficacy outcomes and common reported AEs were weighted by study sample size and calculated using StatsDirect software (version 3, StatsDirect Ltd, Cheshire, UK).

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