Disease activity guided dose reduction and withdrawal of adalimumab or etanercept compared with usual care in rheumatoid arthritis

SCIENCE

Clinical Research

Key Take-Away:

Tumor Necrosis Factor (TNF) inhibitors, adalimumab or etanercept are the usual prescription drugs for rheumatoid arthritis but long term treatment with such drugs is costly and may produce adverse effects. This engenders the need to optimize the dose of TNH inhibitors and its effect on disease activity.

To evaluate whether a disease activity guided strategy of dose reduction of two tumour necrosis factor (TNF) inhibitors, adalimumab or etanercept is non-inferior in maintaining disease control in patients with rheumatoid arthritis compared with usual care.

ABSTRACT:
Background:

To evaluate whether a disease activity guided strategy of dose reduction of two tumour necrosis factor (TNF) inhibitors, adalimumab or etanercept is non-inferior in maintaining disease control in patients with rheumatoid arthritis compared with usual care.

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Methods:

This Randomised controlled, open label, non-inferiority strategy study enrolled in 180 patients with rheumatoid arthritis and low disease activity were selected from two rheumatology outpatient clinics in the Netherlands, from December 2011 to May 2014.

121 patients were allocated to the dose reduction strategy and 59 to usual care. Disease activity guided dose reduction (advice to stepwise increase the injection interval every three months, until flare of disease activity or discontinuation) or usual care (no dose reduction advice). Flare was defined as increase in DAS28-CRP (a composite score measuring disease activity) greater than 1.2, or increase greater than 0.6 and current score of at least 3.2. In the case of flare, TNF inhibitor use was restarted or escalated. Difference in proportions of patients with major flare (DAS28-CRP based flare longer than three months) between the two groups at 18 months, compared against a non-inferiority margin of 20%. Secondary outcomes included TNF inhibitor use at study end, functioning, quality of life, radiographic progression, and adverse events.

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Results:

Dose reduction of adalimumab or etanercept was non-inferior to usual care (proportion of patients with major flare at 18 months, 12% v 10%; difference 2%, 95% confidence interval −12% to 12%).

Dose reduction of adalimumab or etanercept was non-inferior to usual care (proportion of patients with major flare at 18 months, 12% v 10%; difference 2%, 95% confidence interval −12% to 12%). In the dose reduction group, TNF inhibitor use could successfully be stopped in 20% (95% confidence interval 13% to 28%), the injection interval successfully increased in 43% (34% to 53%), but no dose reduction was

possible in 37% (28% to 46%). Functional status, quality of life, relevant radiographic progression, and adverse events did not differ between the groups, although short-lived flares (73% v 27%) and minimal radiographic progression (32% v 15%) were more frequent in dose reduction than usual care.

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Conclusion:

A disease activity guided dose reduction strategy of adalimumab or etanercept to treat rheumatoid arthritis is non-inferior to usual care with regard to major flaring, while resulting in the successful dose reduction or stopping in two-thirds of patients.

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Link to the source: http://www.bmj.com/content/350/bmj.h1389/rapid-responses

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Translated by:

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Exploratory, Tumour necrosis factor (TNF) inhibitors, Randomised Controlled, Open Label, Non-Inferiority Strategy Study, Das28-CRP