

infliximab, respectively, were necessary in order to achieve similar levels of cost-effectiveness as secukinumab, whereas discounts as high as 90% for etanercept, 60% for ustekinumab, 55% for adalimumab and 50% for infliximab were necessary to reach similar levels of cost-effectiveness as ixekizumab and brodalumab.

Conclusion According to this economic model, modern anti-IL-17s are highly cost-effective compared to anti-TNFs and anti-IL-12/23. Though discounts may be a way of making anti-TNFs and anti-IL-12/23 more cost-effective, this study indicates that very high levels of discounts would be necessary to achieve this.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

Conflict of interest Corporate-sponsored research or other substantive relationships: employee at LEO Pharma.

6ER-012 EFFICACY AND SAFETY ANALYSIS OF ALEMTUZUMAB IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background Alemtuzumab is a humanised monoclonal antibody against CD52 approved for relapsing-remitting multiple sclerosis (RRMS), which is a progressive illness affecting the central nervous system (CNS).

Purpose The objective of the present study was to evaluate the efficacy and safety of alemtuzumab.

Material and methods A retrospective study was carried out in a university hospital. Patients treated with alemtuzumab were included for the November 2016–November 2017 period. Data was drawn from clinical digital history and visits from the outpatients module. Demographic data (age, gender), clinical data (diagnosis, previous treatments, number of cycles, Expanded Disability Status Scale (EDSS) before and after treatment, number of relapses since the start of alemtuzumab, MRI lesions' evolution) and safety data (adverse events (AE), blood tests) were registered.

Results Twenty-five patients were found, 20 (80%) of whom were females. Mean age was 41.5 (± 9.3). Twenty-three patients (92%) had a diagnosis of RRMS, one (4%) secondary progressive and one (4%) primary progressive. All patients went through the second infusion cycle during the studied period. Twenty-one patients (84%) had received a mean of the previous treatments of 1.9 (± 1.1), the rest of them were naïve. Mean EDSS before treatment was 4.7 (± 1.7) and after was 3.5 (± 2). Between the first and second cycle (1 year), none of them had a relapse. Confirmed by MRI, 16 patients (64%) had a reduction in CNS lesions and six (24%) had no change. The most reported AE during infusion were migraine: 14/25 patients; rash: 9/25 patients; fever: 5/25 patients; pruritus: 3/25 patients; and hypotension 3/25 patients. After infusion, the most reported AE were rash: 12/25, asthma: 6/25, upper respiratory infection: 5/25, candidiasis: 4/25 and insomnia: 4/25. In blood tests, 100% had lymphopaenia, with a mean duration of 6.3 months (± 3.7) after the first cycle and 4.9 months (± 2.9) after the second cycle.

Conclusion Alemtuzumab seems to be an effective treatment for RRMS as shown by the reduction in EDSS before and

after treatment, any relapse between cycles in our population and lesion reduction in the 64% of patients and no change in 24% of patients. Most of the AE were mild, with migraine being more prevalent during infusion and rash after it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5522829/>
No conflict of interest.

6ER-013 A PILOT RANDOMISED DOUBLE-BLINDED PLACEBO-CONTROLLED TRIAL OF PROPHYLACTIC SILDENAFIL IN PRETERM INFANTS AT RISK OF BRONCHOPULMONARY DYSPLASIA

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Background Bronchopulmonary dysplasia (BPD) is associated with poor long-term neurodevelopmental outcomes and an increased readmission risk because of respiratory conditions. Since the 2005 FDA approval of sildenafil for adults with pulmonary artery hypertension, and despite a 2012 black box warning against long-term use in 1–7 years' old children due to increased risk of death at high doses, there has been an increasing trend of utilising the off-label preparation of sildenafil in infants.

Purpose A proof-of-concept randomised double-blind pilot study was conducted to investigate the use of sildenafil in preventing BPD in preterm infants.

Material and methods The pilot trial was conducted in the neonatal intensive care unit of the Women's Wellness and Research Center. Infants with a gestational age of 24^{0/7}–29^{6/7} weeks were eligible if they needed respiratory or oxygen support greater than or equal to 25%, and if they were at post-natal age of <24 hours at randomisation. Forty preterm infants were randomly assigned to receive off-label oral sildenafil (0.5 mg/kg every 6 hours) or a placebo solution, for 1 week. The primary endpoints were the incidence of BPD and death at 36 weeks postmenstrual age (PMA), and the occurrence of side effects. Secondary outcomes included the incidence of BPD and the provision of respiratory support at day 28 of life; duration of oxygen use; fraction of oxygen used at 36 weeks' PMA and 28 days of life; duration of hospitalisation; the incidence of significant retinopathy of prematurity; and severe intraventricular haemorrhage, periventricular leukomalacia, necrotising enterocolitis, patent ductus arteriosus and sepsis.

Results No significant differences were observed between the sildenafil and placebo study groups in mortality (10% vs. 20%, $p=1.00$), respiratory support (30% vs. 25%, $p=0.57$) and side effects (0% vs. 0%) at 36 weeks' PMA. No significant differences were also detected with any of the secondary outcomes.

Conclusion The off-label use of oral sildenafil did not demonstrate benefits in the prevention of BPD nor in reducing mortality in the extreme and very preterm infants. Future studies are needed to support the current off-label use of sildenafil in preventing BPD in this extremely vulnerable population.