Results.– Step 1 has been completed. Baseline characteristics of pts in
Step 1: Mean (SD) age 59 (±14) yrs; 6 M/6F; 9 newly diagnosed, 3
relapsed pts; anti-MPO+ 7 (58%) pts; anti-PR3+ 6 (50%) pts; mean (SD)
screening s-creat 119.4 (±40.5) μmol/L. No SAEs related to CCX168
occurred in Step 1. No rescue CS was required in the treatment period.
One subject’s disease flared up during the follow-up period. Upon
review, an external data monitoring committee recommended con-
tinuation to Step 2. Eight of 12 pts have been enrolled in Step 2 so far.
One patient’s disease flared up prompting rescue CS. The trial is still
blinded.
Discussion.– The partial CS withdrawal step of this Ph 2 trial has been
decided successfully and the final CS withdrawal step is ongoing.
Conclusion.– The oral CSAR antagonist CCX168 could become a new
treatment for patients with ANCA vasculitis.

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Lack of efficacy of tocilizumab in mucocutaneous Behçet’s syndrome: Report of two cases
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Introduction.– Behçet’s syndrome (BS) is a rare multisystem
inflammatory disease. The treatment of BS consists of immunomo-
dulating agents and biologics. Tocilizumab, an IL-6 inhibitor, have
shown efficacy in BS patients with resistance to other therapies
disease [1,2].

Methods.– We present hereby two patients of Norwegian ancestry with
severe mucocutaneous BS who failed to respond to treatment with the
IL-6 inhibitor tocilizumab.

Results.–
- A 55-year-old woman was primarily treated with high doses of
  glucocorticosteroids with regression of mucocutaneous disease. How-
  ever, the addition of colchicine, methotrexate, azathioprine, anti-TNF-a
  led to either short efficacy or side effects. After the first infusion of
tocilizumab, a deterioration of mouth and genital ulcers was observed
and the patient was admitted to the internal medicine ward with severe
retrosternal pain. The pain responded promptly to a combination
of analgesics and 20 mg of prednisolone.
- A 26-year-old woman with mucocutaneous BS received initially high
to moderate doses of corticosteroids. On the other hand, corticosteroid-
sparing treatment with cyclosporine, azathioprine, colchicine, metho-
trexate, anti-TNF-a led to incomplete response or improper toxicity.
Tocilizumab treatment was started and she received 3 monthly infu-
sions, in total. Partial response was seen during the first two infusions,
howerver, immediately comes after the third infusion the painful genital ulcers
recurred.

Discussion.– Our report comes in contrast with others that described
efficacy of tocilizumab in severe neurological and ocular BS. It appears
that IL-6 is a major contributor in the inflammation observed in
neurological and ocular BS through stimulation of proliferation of Th17
cells [3]. Nevertheless, in mucocutaneous BS the pathogenesis may be
somewhat different, with different cytokine profile than the other
phenotypes of BS [3]. This may explain the inefficacy of tocilizumab in
mucocutaneous BS.

Conclusion.– Tocilizumab may be ineffective in the treatment of mu-
cocutaneous BS.

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with a humanized anti-interleukin-6 receptor antibody, tocilizumab.

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P208

Improving the quality and safety of intravenous cyclophosphamide (IV CYC): A regional audit of a
best-practice protocol
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Introduction.– Following the 2009 Department of Health report “Che-
motherapy Services in England: Ensuring quality and safety” a regional
best-practice protocol for the use of IV CYC was developed. The protocol
contains IV CYC regimes with trial evidence, guidance on steroid
tapering and improving host defence. We audited the protocol stand-
ards and outcome of IV CYC use.

Methods.– Retrospective notes review of all patients at three centres
commencing IV CYC between April 2010 and April 2012.

Results.– Sixty-seven patients received IV CYC (41 at Trust 1, 11 at Trust
2 and 15 at Trust 3). Mean age was 59 years. Indications were: Systemic
Vasculitis 37 (GPA 16, EGPA 4, MPA 5, CNS vasculitis 3, other Vasculitis
9); SLE 5; Scleroderma 6; I LD 16; Other CTD 3. Most Vasculitis patients
received the IV CYC protocol currently being used in the MYCYC trial. All
SLE patients received the Euro-Lupus regime. Doses were adjusted for
age in 85% and renal function in 100%. Anti-emics and Mesna were
prescribed in 100%. Counselling and consent were documented in
> 90%. Formal disease activity assessment and vaccinations were
recommended in 48 and 46% respectively, with some variation be-
 tween centres.

Twenty-five percent of patients had a documented infection during
 treatment, most commonly LRTI or oral candida. Thirty-eight percent
had an adverse event (AE) whilst on CYC; 27% could be attributable to
CYC. The most common AE was nausea ± vomiting in 10%. There were
four deaths during treatment; one could be attributable to CYC. Three
patients did not complete the treatment course (1 withdrew consent, 1
AE, 1 primary inefficacy).

Discussion.– Most patients completed the treatment course. Infections
were common, but usually mild, with no admissions for neutropenic
sepsis. Areas for improvement include: improved formal assessment of
disease activity, documentation of immunization status, and continued
need to communicate with patients and primary care.

Conclusion.– The regional protocol is being followed well in most
domains. It has enabled standard evidence based regimes to be used
across units.

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