TMR5 (Zedupex™) is a product of a Kenyan medicinal plant, prepared as a lyophilized extract and a cream. The products have been evaluated for preclinical safety and efficacy in suitable *in vitro* and *in vivo* systems of herpes infections. Herpes is a viral infection affecting over 60% of the sub-Saharan Africa young adult population. It is caused by two similar viruses, HSV-1 and HSV-2 which share 50% gene sequence homology. The infection in a major cause of genital ulcer disease, associated with increased risks of HIV acquisition and transmission. The aim is to develop TMR5 as an alternative anti-herpes agent, this being necessitated by increased resistance to available drugs and the cost of the drug of choice, acyclovir, in the region. Using the trypan blue exclusion test, plaque inhibition and viral yield reduction assays for assessment of cytotoxicity (CC_{50}) and efficacy (EC_{50}), and Mice and guinea pig cutaneous and genital HSV infection models respectively following oral and topical treatments, TMR5 exhibited no cytotoxicity in mammalian cell lines with a wide therapeutic index ($CC_{50} \geq 58.5 \pm 4.6\mu g/ml$). An EC_{50} of $\leq 14.7 \pm 3.7\mu g/ml$ for both wild type and resistant strains of HSV was realised in plaque and viral yield assays. Oral (250 mg/kg) and topical (10% cream) administrations exhibited significant delay in onset of infections, hindered progression of infection to lethal forms with increased mean survival times and low mortality in both mice and guinea pig models. No acute toxicity has been realised at the therapeutic concentrations. TMR5 has demonstrated a high potential as an anti-herpes agent and arrangements are presently underway to evaluate its efficacy and safety in human clinical trials. A pilot production scheme supported by the National Commission for Science, Technology and Innovation (NCSTI) of Kenya has been undertaken as means of developing TMR5 as an alternative management therapy for herpes infections.

P2.181 IL-4, IL-10 AND TNF-A PROFILE IN NORTH-EASTERN UKRAINIAN HIV-1 INFECTED INDIVIDUALS WITH DIFFERENT LEVEL OF IMMUNODEFICIENCY

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Background Aim of the study was to determine the IL-4, IL-10 and TNF-α profiles in plasma of north-eastern Ukrainian HIV-1 infected individuals with different CD4 T-cell levels.
Methods We used a immunoassay method to measure IL-4, IL-10, TNF-α in plasma of 118 HIV-1 infected people among whom there were 80 (67.8%) men and 38 (32.2%) women aged (32.61 ± 0.87) years. Patients were divided into groups depending on the levels of CD4 T lymphocytes. Group I included 52 people with T-helper cell counts ≥ 350 cells/μL, group II - 66 patients with T-helper cell counts ≤ 200 cells/μL. Comparison group consisted of 30 normal healthy individuals.
Results In the cytokine profile of HIV-1 infected people the increased levels of pro-inflammatory cytokine TNF-α compared to controls (group I - (0.77 ± 0.08), group II - (2.34 ± 0.69), healthy controls - (0.51 ± 0.32) pg/mL, $p < 0.05$) and the anti-inflammatory IL-10 (group I - (3.99 ± 0.99), group II - (20.08 ± 0.44), healthy controls - (1.68 ± 0.32) pg/mL, $p < 0.001$) were demonstrated. No significant difference in IL-4 between surveyed troops and comparison group was found.

Patients with CD4 T lymphocyte levels ≤ 200 cells/μL showed significantly higher plasma concentration of TNF-α and IL-10 compared with the group I ($p < 0.05$). Among HIV-1 infected from group II mean serum concentrations of TNF-α higher than that of group I in 3 times ($p < 0.05$). A significant increase in the concentration of IL-10 detected in patients with severe immunodeficiency (IL-10 levels in group II was 5 times higher, $p < 0.05$), which may indirectly indicate a more active involvement of IL-10 during disease progression.

Conclusion HIV-1 infection was associated with an increase in levels of TNF-α and IL-10. Immune imbalance due to changes in concentrations of cytokines is more pronounced in HIV-infected individuals with severe immunosuppression with CD4 T lymphocyte counts ≤ 200 cells/μL.

P2.182 MALE GENITAL DERMATOSES IN HIV

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Background Little information exists about penile squamous cell carcinoma (PSCC), penile carcinoma in situ (PCIS) and male genital lichen sclerosus (MGLSc) in HIV.
Methods A retrospective review of case notes was performed on HIV-positive men who had presented to specialised Male Genital Dermatoses Clinics between May 2011 and February 2013.
Results 39 men were identified. The mean age at diagnosis was 48 years (range 26 – 71 years). The mean diagnostic delay was 20 months (range 1 – 72 months). 35 were uncircumcised at presentation (4 were circumcised at birth/childhood). The majority of the cases had PCIS (21); 8 had MGLSc, 2 had lichen planus (GLP), 2 had PSCC and the remaining cases had more than one diagnosis (1 had PSCC and MGLSc, 2 had PSCC and PCIS, 3 had PCIS and MGLSc); 6 men had co-existing anal dysplasia (2 had anal SCC); 36 were on ARVs. All genital dermatoses were treated according to our conventional practise. The majority (31) is in remission; 6 have residual disease and receive ongoing treatment (1 GLP, 1 MGLSc and 4 PCIS); 2 have been lost to follow-up; most (32) have been circumcised (including 4 circumcised at birth/childhood). 1 has a short foreskin hence circumcision is not indicated.
Conclusion Advances in ARV treatment have improved the survival of individuals with HIV. This has led to increased interest in long-term morbidities, including cancer. MGLSc and PCIS can progress to invasive cancer. The risk of PSCC in HIV despite ARV treatemnt is x5–6. The presence of the foreskin confers cancer risk. Uncircumcised HIV men should be counselled about the risk of PSCC. There may be an argument for prophylactic circumcision in high-risk cases such. Certainly, clinicians should enquire about the genital health of HIV-positive men and undertake regular (ano) genital examination at follow-up.

P2.183 CLIMACTERIC SYMPTONS AND ASSOCIATED FACTORS IN HIV SEROPOSITIVE WOMEN

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Background In the menopausal transition, the occurrence of insomnia, genito-urinary, psychological and.vasomotor symptoms may occur and this may be aggravated by the diagnosis of HIV infection.
Methods Cross-sectional study including 273 HIV-infected and 264 HIV uninfected Brazilian women. They were submitted to an interview to assess climacteric symptoms, socio-demographic characteristics and weight and height measurement.
Results The average age was 47.7 ± 5.8 years in HIV seropositive women and 49.8 ± 5.3 years in seronegative ($p < 0.001$). Bivariate analysis showed a lower prevalence of vasomotor symptoms in the HIV-positive Group ($p = 0.009$), specifically hot flushes ($p < 0.002$) and sweating ($p = 0.049$). Vaginal dryness was less prevalent in HIV-positive ($p < 0.005$). Depression and insomnia showed no statistical