

PD48 OTL38, A Tumour-Specific Agent In Surgery For Ovarian Cancer

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INTRODUCTION:

Ovarian cancer (OC) has the highest mortality rate of all gynecologic malignancies. Completeness of cytoreductive surgery is a key prognostic factor for survival. To differentiate clearly between malignant and healthy tissue is essential for achieving complete cytoreduction. Using current approaches, this differentiation is difficult and can lead to incomplete tumour removal. OTL38 is a folate analogue conjugated to a near-infrared fluorescent dye which has high specificity and affinity for folate receptor alpha (FR α) expressed in OC. OTL38 together with a specific imaging system can help the surgeon to visualize diseased tissue. The objective of this work is to know the effectiveness and safety of OTL38 in of OC surgery.

METHODS:

Early assessment of OTL38 identified through the early-awareness and alert-system, "SINTESIS-new technologies", of AETS-ISCIIE. The searched databases were: PubMed, WOS, Tripdatabase, Dynamed, Cochrane Library and ICTRP. Clinical studies using the OTL38 in cytoreductive surgery in OC published until September 2017 were reviewed.

RESULTS:

Only one publication, supported by industry, was retrieved. The study assesses the pharmacokinetics and tolerability of OLT38 in 30 healthy people randomized into 4 groups with different doses and a control group. The study also analyses the percentage of cytoreduction in 12 OC patients. Infusion of 0.025, 0.05, and 0.1 mg/kg OTL38 doses was associated with mild adverse events which did not require intervention. The 0.2 mg/kg dose was associated to adverse events of moderate severity. In OC patients, 0.0125 mg/kg dose was considered the optimal dose with mild adverse events. OTL38 accumulated in FR α -positive tumours and metastases allowed the surgeon to resect an additional 29 percent of malignant lesions which were not detected using standard inspection and palpation methods.

CONCLUSIONS:

The OTL38 is an emergent health technology, which could help in cytoreductive surgery for ovarian cancer. However, the evidence is scarce and it would be necessary to continue further studies.

PD49 Social Preferences In HTA: A Pilot Analysis In CLN2 Disease

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INTRODUCTION:

It is established that the current cost effectiveness health technology assessment (HTA) paradigm does not appropriately value rare disease technologies. Social willingness-to-pay (SWTP) has been suggested to be higher for rare disease technologies, it's inclusion into existing HTA framework could better reflect social preferences (SP) and enable a more equitable evaluation of rare disease technologies. Our study aims to estimate SP and SWTP for a rare disorder, CLN2 disease.

METHODS:

Relevant attributes for CLN2 disease were developed and validated by literature review and focus groups with patient's primary caregivers. An elicitation survey (discrete choice experiment (DCE) WTP and relative social willingness to pay (RS-WTP)) was developed using the selected attributes and levels of each attribute. The survey instruments and attributes/levels were tested and validated in a pre-pilot survey (n = 103) and a subsequent pilot survey (n = 286) of the United Kingdom (UK) general population. Information about CLN2 disease was provided to respondents and their understanding of the disease was tested including assessment of framing effects. The main survey with the general UK population (n = 4,009) is now complete.

RESULTS:

Eight hundred and twenty-six people were contacted, of which 286 completed the DCE, 113 abandoned the survey before the DCE and 92 abandoned after the DCE. There were no significant differences in characteristics

of respondents completing the DCE and those starting but not completing the DCE. Median survey completion time was 20 minutes with 90 percent of participants completing in a single sitting. Median score for the understanding test was 3 (Min = 0 and Max = 4). Incoherencies in WTP estimates were analyzed enabling us introduce relevant modifications and select the most appropriate attribute levels.

CONCLUSIONS:

DCE and RS-WTP potentially are appropriate methods for assessment of social preferences. The selected attributes/levels for the experiment in CLN2 disease have been validated in this pilot.

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PD50 Helping Innovators Navigate Policy And Regulatory Processes

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INTRODUCTION:

As part of a national aging and technology network, AGE-WELL, one work group aims to promote the understanding of potential policy and regulatory hurdles among innovators and decision-makers. This study describes the development of resources to help innovators to navigate policy and regulatory systems to have their technologies adopted.

METHODS:

A policy primer was created that highlights considerations for innovators during the innovation process (from development to implementation). The content of the policy primer was developed by identifying resources through the Canadian Agency for Drugs and Technology in Health Grey Matters search tool, and in consultation with legal and regulatory consultants. By surveying AGE-WELL technology-developing projects (n=15) we characterized the technologies being developed within the network. Survey questions included: intended end-user/purchaser of the technology and past/anticipated facilitators/barriers in their innovation process. The policy primer and survey data were combined to create tailored innovation maps with considerations for each

technology being developed within the network. These materials were used to develop a beta website where users can receive information relevant to various innovation stages, as it pertains to their technology. We gained feedback about our materials via surveys and interviews with AGE-WELL technology developers.

RESULTS:

The tailored innovation maps and website were seen as helpful resources for understanding policy and regulatory processes required for technology adoption. Technology developers expressed interest in gaining further access to these resources. Innovators desired additional resources about demonstrating value and measuring technology effectiveness.

CONCLUSIONS:

Resources were developed to help guide technology innovators through policy and regulatory processes; preliminary feedback suggests these were valued by innovators. Next steps include refining the website and releasing these resources to innovators beyond the AGE-WELL Network.

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PD53 Efficacy And Safety Of Nicotinamide In Hemodialysis Patients

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INTRODUCTION:

Hyperphosphatemia is a most common problem in dialysis patients. Phosphorus imbalance in dialysis patients increases the risk of developing the bone mineral disorder and cardiovascular mortality. Randomized controlled trials (RCTs) presented variable findings concerning the reduction of phosphorous level in nicotinamide user. So, this systematic review is aimed to explore the efficacy and safety of nicotinamide in hemodialysis patients.

METHODS:

This systematic review was conducted by adhering to the PRISMA guidelines. Study for inclusion was identified by running the suitable keywords in