Development of a Novel Aspirin Suppository Formulation and Evaluation of the Acetylation of COX-1 Via a HT-29/Caco-2 Cell Absorption Assay Used to Detect the Absorption of Aspirin Formulated With Various Bases and Excipients

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STATEMENT OF THE PROBLEM

Background
Aging Baby-boomer Population
• Aspirin use increases with age. The aging baby-boomer population is resulting in more patients who are not able to take medication orally (NPO).
• Rectal suppositories are the commonly used alternative for NPO patients.

Current Aspirin Suppositories
• Only one is available from Paddock labs. Previous research does not specify if this was the formulation used.
• Very little research is available concerning aspirin suppositories.

Current research is dated and more foundational in nature rather than comprehensive and adequately powered
• A study concluded that rectal absorption of aspirin was slow and long in duration whereas a study by Broom stated that serum levels were short-lived.
• The most foundational were a series of studies from the seventies that involved very small sample sizes and were inadequately powered.

Mechanism of Action
Aspirin is hydrolyzed to the active component salicylate by esterases in the GI mucosa, red blood cells, synovial fluid, and blood.
Aspirin irreversibly inhibits cyclooxygenase-1 and 2 (COX-1 and 2) enzymes via acetylation.
This causes a decrease in the formation of prostaglandin precursors and irreversibly inhibits the formation of thromboxane A2, thus inhibiting platelet aggregation.
This action also has antiplatelet, antaggregating, and anti-inflammatory benefit.

Significance of the Problem
• The demand for dosage forms that accommodate patients who can take nothing by mouth
• The absorption of the current aspirin suppository available is poor and erratic
• There is a need for a better aspirin suppository product to enhance absorption and therapeutic effect.

OBJECTIVES
To create a novel aspirin suppository with increased absorption of cells.

ALTERNATIVE HYPOTHESIS
• The inclusion of zinc and carnosine excipients and selected bases in the formulation of aspirin (or sodium salicylate) suppositories increases the absorption in HT-29 colonic adenocarcinoma cells or Caco-2 cell lines.

REFERENCES
4. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. January-May 2014 Obtain the assay, reagents, and aspirin
5. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. August-December 2013 Research proposal development
6. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. August-December 2014 Assay validation
7. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. January-May 2015 Test and evaluate aspirin suppository formulations
8. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. August-December 2015 Propose human studies
9. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. January-May 2016 Conduct study
10. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. September-December 2016 Conduct study
11. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. January-May 2017 Conduct study
12. Development of a novel aspirin suppository formulation and evaluation of the acetylation of COX-1 via a HT-29/Caco-2 Cell absorption assay used to detect the absorption of aspirin formulated with various bases and excipients. August-December 2017 Conduct study

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