

The evaluation of the efficacy and safety of a transdermal delivery system of nicotine /mecamylamine in cigarette smokers

Submission date 03/05/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/03/2010	Condition category Other	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

To determine the efficacy and safety of nicotine transdermal therapy co-administered with the nicotine antagonist, mecamylamine; as compared to a nicotine transdermal patch alone (21 mg nicotine + 6 mg mecamylamine, 21 mg nicotine + 3 mg mecamylamine, and 21 mg nicotine + 0 mg mecamylamine).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the West Virginia University's Institutional Review Board in 1997, reference number: HS13781

Study design

Multicenter (n=4), double-blind, randomized, parallel group, repeat dose study

Primary study design

Intentional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cigarette smoking

Interventions

Treatment was administered for the first six weeks of the 8-week study. Patients were instructed to continue smoking for the first two weeks of treatment.

Patients were randomised into one of the following groups:

1. 21 mg nicotine + 6 mg mecamylamine
2. 21 mg nicotine + 3 mg mecamylamine
3. 21 mg nicotine + 0 mg mecamylamine

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mecamylamine, nicotine

Primary outcome(s)

Analysis of the four-week continuous abstinence for the intent-to-treat population using the slip definition, which allows smoking in the first two weeks after the quit date.

Key secondary outcome(s)

Analysis of the four-week continuous abstinence for the intent-to-treat population using the strict definition (no smoking after the quit date).

Completion date

31/12/1998

Eligibility

Key inclusion criteria

1. Males or females motivated to quit smoking between the ages of 18 and 70 years
2. Smoked at least 20 cigarettes a day for three years or more (smoking confirmed via expired CO level >10 ppm).

All subjects had normal blood pressure and heart rate, weighed more than 100 pounds and typically no more than 130% of their ideal body weight, and expressed willingness to quit smoking on the specified target quit date (TQD). They were not currently using smokeless tobacco or other nicotine products. A detailed medical history, routine physical examination, laboratory tests and electrocardiogram (ECG) confirmed that subjects were in general good health. All women had a negative pregnancy test and agreed to use a medically accurate contraceptive method.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Participants were excluded if they had a history of significant hepatic, renal, endocrine, cardiac, psychiatric, gastrointestinal, pulmonary, or metabolic disorder including hyperthyroidism, pheochromocytoma, diabetes, severe coronary insufficiency, recent myocardial infarction (within 90 days), glaucoma, cerebrovascular disease, stroke, chronic renal failure, prostatic hypertrophy, prostatic disease, bladder neck obstruction, urine retention, urethral stricture, a history of atopic or eczematous dermatitis, psoriasis, or altered skin condition at patch application site.

Date of first enrolment

01/01/1997

Date of final enrolment

31/12/1998

Locations

Countries of recruitment

United States of America

Study participating centre
University of Maryland
Maryland
United States of America
20742

Sponsor information

Organisation
Elan Corp (USA)

ROR
<https://ror.org/013t2n957>

Funder(s)

Funder type
Industry

Funder Name
Elan Corp (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2007		Yes	No