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Use of imaging to identify reused seasonal hollow chocolate figurines and prevent their distribution in a hospital setting

Submission date
11/06/2020

Recruitment status
No longer recruiting

Registration date
02/07/2020

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Not Specified

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Germany, and probably other European countries celebrating both Easter and Christmas, it is a widespread urban myth that leftover chocolate Easter bunny figurines are rewrapped in seasonal tin foils simply to be resold as chocolate Santa Clauses (and vice versa).
The German Confectionary Association (BDSI) repeatedly denies this accusation (e.g. https://www.confectionerynews.com/Article/2013/04/16/Chocolate-santas-made-from-Easter-bunnies-denials), as it would be against food and hygiene legislation to reuse already supplied products.
There is, however, limited evidence to prove either the truth of the myth nor its contradiction by the industry. As chocolate Easter bunnies and Santa figurines are common gifts to both health-care professionals and inpatients, scientific information is needed to guarantee they do not contain potentially toxic edibles. Expired chocolate may be "bloomed", indicated by a grey or white film over the surface caused by aged and degraded cocoa fat or sugar. While there is little information that consumption of expired chocolate is harmful, any chance of food poisoning must be minimised, specifically in hospital settings.
Researchers from Manchester showed that computed tomography (CT) is a suitable imaging tool to unveil the internal structure of complex (seasonal) sweets like chocolate rabbits, Kit Kat, or Ferrero Rocher (https://www.cnet.com/news/easter-chocolates-look-gross-in-xray-computer-3d-scans). These results had not been published in a peer-reviewed scientific journal. So far, no study compared the morphometric features of either seasonal (i.e., Easter and Christmas) chocolate figurines which may provide some hint if they had already been on the shelf in the foregone season. We consider the figurines' shape one of many possible indicators of recycling, as unsold chocolate may also have been melted and again found its way to a casting mould.

Who can participate?
Health care professionals and patients at the trial participating centres

What does the study involve?
Main observational units are Easter Bunny and Santa Clause hollow-chocolate figurines undergoing whole-body computed tomography. In addition, volunteers passing by among main

entrances of the trial centres will be approached by research assistants to fill out the 5-item GRINCH questionnaire on personal beliefs about chocolate consumption and safety.

What are the possible benefits and risks of participating?
This study poses nil risk to investigated objects or humans, but also does not promise any benefit to participants.

Where is the study run from?
1. BG Klinikum Unfallkrankenhaus Berlin gGmbH (Germany)
2. BG Klinikum Duisburg (Germany)
3. BG Kliniken - Klinikverbund der gesetzlichen Unfallversicherung gGmbH (Germany)

When is the study starting and how long is it expected to run for?
April 2020 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Dirk Stengel, Dirk.Stengel@bg-kliniken.de

Contact information

Type(s)
Scientific

Contact name
Prof Dirk Stengel

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CRECHE_V1.4_BGK_11062020

Study information

Scientific Title
Computed tomography to rebut the myth that Easter and Christmas hollow chocolate figurines are reused and are edible safely

Acronym
CRECHE

Study objectives
1. The belief that reuse and rewrapping of seasonal (hollow) chocolate figurines occurs is false
2. Low-dose CT imaging is a rapid and reliable screening tool to determine whether a shaped chocolate gift may be a remain of its sweet predecessor
3. Potential consumers (both health-care professionals and patients) will consider it safe to taste and eat these figurines once CT precluded it is a reused product

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/06/2020, IRB of the Ärztekammer Berlin (Ethik-Kommission, Ärztekammer Berlin, Friedrichstr. 16, 10969 Berlin, Germany; +49 30 40806 2601; stefan@mueller-lissner.de), ref: none

Study design
Multi-centre prospective observational study and survey

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Health implications of reused seasonal chocolate figures

Interventions
A questionnaire will be distributed to both health care professionals and patients to ask for their belief in the urban myth, their willingness to consume chocolate Santas (given the chance they are Easter remains) and any previous exposure to expired seasonal sweets.

Easter and Christmas chocolate figurines will undergo computed tomography with three-dimensional image reconstruction, food chemistry analyses to determine the age of ingredients. Whole-body computed tomography with three-dimensional reconstruction

Intervention Type
Other

Primary outcome(s)
Contour-Rating Scale (CRS), as assessed by two independent radiologists

Key secondary outcome(s))
1. Maximal length, breadth and depth the minimum, the mean and maximum thickness of the chocolate mantle, as well the minimum, mean, and maximum thickness of the figurine’s bottom or stand measured (mm) radiologically at a single timepoint
2. Radiation exposure (e.g. volume CT dose index, dose-length-product), scanning time, and time

from arrival in the CT suite until the availability of morphologic measures at a single timepoint
3. Health-care professionals' and patients' belief in the urban myth that left-over chocolate Easter figurines are rewrapped and sold as Santas, and their willingness to consume chocolate Santas, given CT precluded they had been reused, measured by Likert-scales at a single timepoint
4. Consumption of expired chocolate and symptoms of food-poisoning thereafter measured using a novel questionnaire at a single timepoint

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Survey:
1. Health-care professionals (i.e., doctors, nurses)
2. Patients from the two participating institutions

Radiological measurement:
3. Easter chocolate figurines of different size and shape from various German manufacturers, purchased between April 01 and May 31 2020, and Christmas chocolate figurines of different size and shape from various German manufacturers, to be purchased from their first availability in stores and supermarkets (presumably early September 2020).

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2020

Date of final enrolment
20/09/2020

Locations

Countries of recruitment
Germany

Study participating centre
BG Klinikum Unfallkrankenhaus Berlin gGmbH
Warener Str. 7
Berlin
Germany
12683

Study participating centre
BG Klinikum Duisburg
Großenbaumer Allee 250
Duisburg
Germany
47249

Study participating centre
BG Kliniken - Klinikverbund der gesetzlichen Unfallversicherung gGmbH
Leipziger Pl. 1
Berlin
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Sponsor information

Organisation
BG Kliniken - Klinikverbund der gesetzlichen Unfallversicherung gGmbH

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/12/2021	14/12/2021	Yes	No
Protocol file	in English version V1.4	13/06/2020	02/07/2020	No	No
Protocol file	in German version V1.4	13/06/2020	02/07/2020	No	No