U.S. Businesses using ClinicalTrials.gov to market unproven and unlicensed stem cell interventions

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Businesses in the US are registering pay-to-participate stem cell studies on ClinicalTrials.gov. A recent examination of clinical studies registered on ClinicalTrials.gov revealed multiple study listings that have not been appropriately reviewed and cleared by the FDA and are being conducted by businesses that charge study participants. To avoid the erosion of public trust in the database, studies submitted to ClinicalTrials.gov need to be properly screened before being registered and listed.

What questions & challenges are raised?

The clinical trial process was developed over many years to test the safety and effectiveness of new medical treatments. In the US, the Food and Drug Administration (FDA) oversees drugs, medical devices, and biologics that require pre-marketing authorization. The FDA reviews such studies before clearing them or placing them on clinical holds. Sponsors and investigators conducting such studies must provide the FDA with sufficient scientific evidence before drugs, biologics, and medical devices are approved or licensed for use. The searchable database at ClinicalTrials.gov was developed by the National Institutes of Health (NIH) to make the clinical trial process more transparent and allow individuals to find relevant studies. However, studies submitted to ClinicalTrials.gov for listing are not screened to confirm that businesses conducting clinical studies are compliant with applicable regulatory, ethical, and scientific standards. Dr Leigh Turner from the University of Minnesota has examined the listings on ClinicalTrials.gov and found that U.S. businesses and international studies are using the platform to market pay-to-participate clinical studies in which individuals are charged thousands or tens of thousands of dollars to receive unproven and unapproved stem cell interventions. Dr Turner’s research shows that some businesses use their listings on ClinicalTrial.gov in an attempt to legitimise themselves by affiliating themselves with an NIH operated website.

What insight & direction does this give for research policies?

Perhaps the largest concern expressed by Dr Turner is that unproven and unapproved stem cell interventions harm individuals. Dr Turner notes several cases of patients who have been injured at clinics selling unproved stem cell interventions. Dr Turner also mentions that some individuals have filed lawsuits for harms allegedly resulting from the administration of unproven stem cell interventions, some of which were provided in the context of studies listed on ClinicalTrials.gov. Allowing unverified listings on ClinicalTrials.gov risks allowing businesses to conduct clinical studies on a for-profit basis while offering little prospect of meaningful scientific knowledge. Dr Turner describes several ways in which pay-to-participate ‘clinical studies’ are often poorly designed. Frequently, proper controls are not in place and patients may experience perceived benefit as a result of the placebo effect. Furthermore, pay-to-participate studies often do not report results in credible peer-reviewed journals for all their study subjects. Instead, they often report specific cases with purported positive results while failing to disclose cases that injured patients or produced no effects. The failure to screen listings on ClinicalTrials.gov also risks causing confusion between legitimate clinical trials on stem cell treatments with businesses offering unsubstantiated and unapproved stem cell treatments. This blurring of important distinctions undermines the public’s trust in clinical trials, stem cell research, and ClinicalTrials.gov. Dr Turner closes his article by urging the government to fund proper screening of clinical trials listed on ClinicalTrials.gov. Adequate review of submitted studies will better protect study subjects and the field of legitimate stem cell research.

What background and point are discussed?

The US has federal regulations that classify different forms of treatments and dictate what procedures and reviews must occur before clinical trials are permitted to commence. Dr Turner’s investigation revealed numerous clinical studies listed on ClinicalTrials.gov that use stem cells (and other cell mixtures) generated by collecting and processing a patient’s own fat tissue, bone marrow, blood, or other bodily tissues. Representatives from several stem cell businesses claim that the stem cells administered in their studies meet specific criteria that exempt them from FDA oversight in the form of reviewed and cleared Investigational New Drug applications. However, Dr Turner provides an extensive list of references showing that the FDA classifies stem cells obtained using methods described in these studies as biological products or drugs. Therefore they should undergo review by the FDA before clinical trials begin. Numerous clinical studies listed on ClinicalTrials.gov were shown by Dr Turner to require patients to pay fees. Yet, these studies do not appear to have obtained permission from the FDA to charge study subjects, as federal regulations require. Some listings state that their study is ‘Patient-funded’, ‘patient-sponsored’ or ‘self-funded’ but many listings do not disclose on ClinicalTrials.gov that study subjects are charged fees to participate. Well-designed, scientifically sound clinical studies typically examine the effect of a new investigational agent on a specific disease or injury. Surprisingly, many pay-to-participate clinical studies include study subjects with a wide range of diseases and injuries. For example, one company cited by Dr Turner claims to be assessing the use of cells isolated from fat tissue to treat neurodegenerative diseases, erectile dysfunction, autoimmune diseases, cardiomyopathies, emphysema, lung conditions, Parkinson disease, ALS, and other diseases and injuries. This clinical study aims to enrol 3000 subjects, but doesn’t state on the ClinicalTrials.gov listing that it charges study subjects $6000 or more to enrol. All the businesses found by Dr Turner to be listing questionable clinical studies on ClinicalTrials.gov can be found in his paper “ClinicalTrials.gov, stem cells and ‘pay-to-participate’ clinical studies”.